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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant : Nurhan Pinar Tutuncu, et al.

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Title : A CONFECTIONERY PRODUCT
HAVING A SALIVATION REGION
AND AN ORAL COMFORT
REGION

December 9, 2008

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Commissioner for Patents

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BRIEF ON APPEAL

This is an appeal from the final rejection of Claims 1-5, 7, 8, 10, 11, 13-21, 23, 24, and 28-32 set forth in the Final Office Action dated July 17, 2008 (hereinafter the "Final Office Action"). Notice of Appeal was submitted November 17, 2008.

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BRIEF ON APPEAL

I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Mars Incorporated.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-5, 7, 8, 10, 11, 13-21, 23, 24 and 28-32 have been finally rejected in an Office Action dated July 17, 2008 (hereinafter the "Final Office Action" or abbreviated "OA"). Claims 6, 9, 12, 22 and 25-27 have been cancelled. A Notice of Appeal with the required fee was filed August 7, 2007 appealing the final rejection of claims 1-3, 7, 8, 10, 11, 13-21, 23, 24 and 28. Dependent claims 29-32 were added in an Amendment filed October 7, 2007. After receipt of the Final Office Action, a second Notice of Appeal was filed November 17, 2008.

IV. STATUS OF AMENDMENTS

The claims have not been amended subsequent to the Final Office Action.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention is directed to a hard candy confectionery product having two regions, each having a surface on the exterior of the product: (1) a salivation region in which acidulent is concentrated in a confectionery base; and (2) an oral comfort region, in which a lipid, surfactant or mixture thereof is concentrated in a confectionery base to provide oral comfort. (See page 6, lines 3-16). A commercial embodiment of the claimed invention was sold in the United States for a time under the AQUADROPS® Hydrating Mouth Drops trademark, and is available in other countries today.

As stated in the Summary of the Invention (page 6, lines 18-26),

having the salivation agent concentrated in one region of the product enhances the initial salivation effect and promotes mechanical action or movement of the piece throughout the mouth. In particular, because of the separation of the two regions, greater amounts of salivation agent may be used resulting in an increased initial impact causing enhanced oral manipulation, but still with acceptable taste.

Thus, a concentration that might be found irritating if distributed throughout a product is concentrated in one region, causing the consumer to move the candy in his or her mouth. This movement of the candy in the consumer's mouth in turn enhances the degree of salivation achieved. This aspect of the invention is depicted in a graphic made available to the Examiner in an interview on December 16, 2002

(Exh. E-1).

Independent claim 1 also requires that the salivation region and oral comfort region have a surface on the exterior of the product (see page 10, lines 27-31); that the acidulent is not uniformly distributed throughout the product, but is concentrated in the salivation region (see page 16, lines 1-10); that the oral comfort ingredient is concentrated in the oral comfort region (see page 16, lines 1-10); the confectionery product is a hard candy (see page 15, lines 26-28); and the confectionery product is made of about 50 to about 99.5 percent by weight of confectionery base (see page 9, lines 20-22).

Independent claim 17 recites a method of making the confectionery of claim 1, comprising the steps of mixing the salivation region ingredients and the oral comfort region ingredients, each method step being disclosed in the specification, for

example, at page 7, lines 4-21 (Summary of the Invention) and page 17, line 28 to page 19, line 2 (Example 1).

Independent claim 20 is a method for treating xerostomia (dry mouth) using the confectionery product described in claim 1, described at page 7, line 29 to page 8, line 5 of the specification.

Independent claim 23 is similar to claim 1, but specifies that the confectionery base is selected from either (1) the group consisting of sucrose, glucose, fructose, maltose, corn syrup, and mixtures thereof (see page 8, line 31 to page 9, line 1), or (2) the group consisting of isomalt, erythritol, hydrogenated starch hydrolysates, sorbitol, xylitol, mannitol and mixtures thereof. (See page 9, lines 7-10).

Independent claim 24, is similar to claim 1, but recites that “the acidulent is not uniformly distributed throughout the product but is concentrated in the salivation region to cause movement of the product in the oral cavity.” The functional result of concentrating acidulent and oral comfort ingredient in discrete regions of the product, causing movement of the piece throughout the mouth and simultaneous soothing, is disclosed in the specification at page 16, lines 4-15.

The independent claims are argued separately. The dependent claims 15, 16, 18, 19, 21 and 28-32 are also argued separately. Claims 15, 16, 21, and 28 recite the presence of, and an amount of, cooling agent in the salivation region, in combination with the acidulent (see page 11, lines 3-23). Claims 18 and 19 recite details of the method of making the confectionery, using a mold having separate cavities, separated by a ridge (page 15, lines 18-22; page 17, lines 5-12).

The claims are reproduced in the attached Claims Appendix (Section VIII, A1-A8).

VI. GROUNDINGS OF REJECTION TO BE REVIEWED ON APPEAL

A. References Applied Against the Claims

1. U.S. Patent No. 5,284,659 to Cherukuri, et al. (“Cherukuri”)
2. WO 99/579427 to Le, et al. (“Le”)
3. U.S. Patent No. 4,517,205 to Aldrich (“Aldrich”)
4. U.S. Patent No. 6,004,538 to Hughes (“Hughes”)
5. U.S. Patent No. 6,206,429 to Bealin-Kelly (“Bealin-Kelly”)
6. WO 97/06695 (“Hanke”)¹
7. National Institute of Dental and Craniofacial Research, NIH publication, June 1999 (“the NIH Publication”)
8. U.S. Patent No. 6,099,880 (Klacik, et al.)

B. Issues to be Reviewed on Appeal

1. Whether Claims 1-5, 7-8, 10-11, 13-14, 17, 20, 23-24, 29-32 are obvious under 35 U.S.C. § 103(a) over Cherukuri in view of Le?
2. Whether Claims 18-19 are obvious under 35 U.S.C. § 103(a) over Cherukuri in view of Le, further in view of Aldrich.

¹ Another reference of record in the application, U.S. Patent No. 6,231,900 to Hanke, is the U.S. national phase of WO 97/06695 and was also sometimes referred to in the prosecution history of this application (but not in this Appeal Brief) as “Hanke” or “Hanke I.” The Examiner made several rejections over Hanke I during the course of prosecution. A rejection of claims 20-21 over Hanke I was withdrawn in view of applicant’s arguments (Office Action, July 20, 2006). A rejection of claims 1-5, 7-8, 10-11, 15-18 and 23-24 under Section 103 over Hanke I, and rejections of claims 19-21 under Section 103 over Hanke I, in view of secondary references, were also withdrawn in view of amendments (Office Action, February 8, 2007).

3. Whether Claims 15-16, 21, and 28 are obvious under 35 U.S.C. § 103(a) over Cherukuri in view of Le, further in view of Hughes.

4. Whether Claims 1-5, 7-8, 13-18, 23, 29, 31 are obvious under 35 U.S.C. § 103(a) over Bealin-Kelly in view of Hanke.

5. Whether Claims 20-21 are obvious under 35 U.S.C. § 103(a) Bealin-Kelly in view of the NIH Publication.

6. Whether Claim 19 is obvious under 35 U.S.C. § 103(a) over Bealin-Kelly in view of Hanke, further in view of Klacik.

VII. ARGUMENT

A. Summary

The prior art does not teach or suggest a product having discrete regions, with an acidulent concentrated in one region and a lipid or surfactant concentrated in another region, such that the product can be used as a treatment for xerostomia (dry mouth). The Office Action gathers an acidulent from one reference, a lipid from another reference, and inserts these ingredients arbitrarily in respective regions of a product found to have discrete regions. The rejection rationale disregards how the ingredients are used in the references, and fails even to allege that the “combinations” meet the functional characteristics expressed in the present claims.

B. 35 U.S.C. § 103(a) Legal Analysis

In its decision in *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727; 82 U.S.P.Q.2d 1385 (2007), the Supreme Court reaffirmed the three-part framework for determining obviousness under § 103 set out in *Graham v. John Deere Co.*, 383 U.S. 1; 148 U.S.P.Q. 459 (1966). In *Graham*, it was held that the analysis for determining obviousness is objective:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

Graham 383 U.S. at 17-18; 148 U.S.P.Q. at 467.

Referring to the framework set out in *Graham*, the Supreme Court in *KSR* further stated that, “while the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls.” *KSR*, 127 S.Ct. at 1735; 82 U.S.P.Q.2d at 1391.

On October 10, 2007, the USPTO published “Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in view of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc*” (“KSR Guidelines”). In addition to acknowledging the Supreme Court’s reaffirmation of the *Graham* factors [Exh. E-2, p. 57526 at column 3], the KSR Guidelines specifically state that the “Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. § 103 (a) should be made explicit” [Exh. E-2, p. 57528 at column 3]. The KSR Guidelines provide seven different rationales that may be used to support a finding of obviousness [Exh. E-2, p. 57529 at column 1]. Each of the seven rationales are discussed below.

Rationale 1: Combining Prior Art Elements According To Known Methods To Yield Predictable Results

According to the KSR Guidelines, to reject a claim based on this rationale, the three-part *Graham* analysis needs to be performed and, from that analysis, the patent examiner must “articulate” the following:

- (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;
- (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately;
- (3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

[Exh. E-2, p. 57529 at columns 1-2.]

Rationale 2: Simple Substitution of One Known Element for Another to Obtain Predictable Results

According to the KSR Guidelines, to reject a claim based on this rationale, the three-part *Graham* analysis needs to be performed and, from that analysis, the patent examiner must “articulate” the following:

- (1) a finding that the prior art contained a device (method, product, etc.) which differed from the claimed device by

the substitution of some components (step, element, etc.) with other components;
(2) a finding that the substituted components and their functions were known in the art;
(3) a finding that one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable; and
(4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

[Exh. E-2, p. 57530 at column 1.]

Rationale 3: Use of Known Technique to Improve Similar Devices (Methods, or Products) in the Same Way

According to the KSR Guidelines, to reject a claim based on this rationale, the three-part *Graham* analysis needs to be performed and, from that analysis, the patent examiner must “articulate” the following:

- (1) a finding that the prior art contained a “base” device (method, or product) upon which the claimed invention can be seen as an “improvement;”
- (2) a finding that the prior art contained a “comparable” device (method, or product that is not the same as the base device) that was improved in the same way as the claimed invention;
- (3) a finding that one of ordinary skill in the art could have applied the known “improvement” technique in the same way to the “base” device (method, or product) and the results would have been predictable to one of ordinary skill in the art; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

[Exh. E-2, p. 57530 at column 3.]

Rationale 4: Applying a Known Technique to a Known Device (Method, or Product) Ready for Improvement to Yield Predictable Results

According to the KSR Guidelines, to reject a claim based on this rationale, the three-part *Graham* analysis needs to be performed and, from that analysis, the patent examiner must “articulate” the following:

- (1) a finding that the prior art contained a “base” device (method, or product) upon which the claimed invention can be seen as an “improvement;”
- (2) a finding that the prior art contained a known technique that is applicable to the base device (method, or product);
- (3) a finding that one of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results and resulted in an improved system; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

[Exh. E-2, p. 57531 at columns 1-2.]

Rationale 5: “Obvious To Try” — Choosing from a Finite Number of Identified, Predictable Solutions, With a Reasonable Expectation of Success

According to the KSR Guidelines, to reject a claim based on this rationale, the three-part *Graham* analysis needs to be performed and, from that analysis, the patent examiner must “articulate” the following:

- (1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem;
- (2) a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem;

- (3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

[Exh. E-2, p. 57532 at column 1.]

Rationale 6: Known Work in One Field of Endeavor May Prompt Variations of it for Use in Either the Same Field or a Different One Based on Design Incentives or Other Market Forces if the Variations Would Have Been Predictable to One of Ordinary Skill in the Art

According to the KSR Guidelines, to reject a claim based on this rationale, the three-part *Graham* analysis needs to be performed and, from that analysis, the patent examiner must “articulate” the following:

- (1) a finding that the scope and content of the prior art, whether in the same field of endeavor as that of the applicant’s invention or a different field of endeavor, included a similar or analogous device (method, or product);
- (2) a finding that there were design incentives or market forces which would have prompted adaptation of the known device (method, or product);
- (3) a finding that the differences between the claimed invention and the prior art were encompassed in known variations or in a principle known in the prior art;
- (4) a finding that one of ordinary skill in the art, in view of the identified design incentives or other market forces could have implemented the claimed variation of the prior art, and the claimed variation would have been predictable to one of ordinary skill in the art; and
- (5) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

[Exh. E-2, p. 57533 at column 1.]

Rationale 7: Some Teaching, Suggestion, or Motivation in the Prior Art that
Would Have Led One of Ordinary Skill to Modify the Prior Art Reference or To Combine
Prior Art Reference Teachings to Arrive at the Claimed Invention

According to the KSR Guidelines, to reject a claim based on this rationale, the three-part *Graham* analysis needs to be performed and, from that analysis, the patent examiner must “articulate” the following:

- (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
- (2) a finding that there was reasonable expectation of success; and
- (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

[Exh. E-2, p. 57534 at columns 1-2.]

With respect to determining the appropriateness of references used in combination to reject a claim, the Federal Circuit has consistently held that “it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.” *In re Hedges*, 783 F.2d 1038, 1041, 228 U.S.P.Q. 685, 687 (Fed. Cir. 1986); *In re Wesslau*, 353 F.2d 238, 241; 147 U.S.P.Q. 391, 393 (C.C.P.A.

1965). In the case of *In re Fritch*, 972 F.2d 1260, 1266; 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992), the Federal Circuit forbade “hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” *See also Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050-51; 5 U.S.P.Q. 2d 1434, 1438 (Fed. Cir. 1988) (“The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time.”).

Thus, the case law makes clear that in rejecting a claim under 35 U.S.C. § 103(a), the rejection is to be explicitly articulated; the rejection is not to be based on hindsight; the analysis must not exclude full consideration of portions of the prior art that a person of ordinary skill in the relevant field would take into consideration when evaluating the prior art, even though those portions may not be useful to support a desired argument for rejecting the claim; and it is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior-art elements in the manner claimed.

C. Claims 1-5, 7-8, 10-11, 13-14, 17, 20, 23-24, 29-32 Are Not Obvious Over Cherukuri in View of Le

1. Differences Between the Claimed Invention and the Prior Art

The Examiner relies on Cherukuri as disclosing a confectionery product having regions each having a surface on the exterior of the product, referring to Cherukuri, Figs. 5 and 6 (OA, page 3, lines 1-2). However, the specific composition examples in Cherukuri are center-filled products, and the patent refers to the regions as “Shell” and “Core.” (See, for example, Cherukuri at column 12, Example 1, lines 45-65). The Office Action fails to articulate a reason why one of ordinary skill in the art would have started with an embodiment shown in Figs. 5 and 6.

The Examiner further alleges that these two regions can be constituted with compositions according to Table II, Example III (OA, page 3, lines 15-22; Cherukuri col. 12, lines 1 to 65). In Example III, the “Core” region contains a fat encapsulated flavor composition in a diluent. The Examiner alleges that the “Core” region is similar to the claimed oral comfort region, apparently on the grounds that it contains a lipid encapsulation material (OA, page 3, line 21). The “Shell” region includes breath deodorant, and the Examiner alleges that this region is similar to the claimed salivation region, although it does not contain an acidulent (OA, page 3, line 17).

Notably, the Examiner does not allege that Cherukuri discloses the use of any compound to create salivation, nor that Cherukuri discloses a confectionery product useful to promote salivation. The fat encapsulation in Cherukuri is not disclosed as being present in an amount effective to “lubricate, coat or moisten an oral cavity,” and the Examiner does not allege that it does.

The Examiner alleges that “Le teaches co-processed comestible, confectioneries, pharmaceuticals, and dentrifices comprising an acid and water-soluble crystalline compounds,” and further alleges that Le teaches the use of acids in the prior art for a “variety of reasons” (OA, page 4, lines 8-9). The Examiner also alleges (as it turns out, incorrectly) that acids “reduce plaque” (OA, page 5, line 6).

Le discloses the use of an acid in a chewing gum to increase saliva production, but that is in connection with the description of the Related Art (referring to U.S. Patent No. 5,151,270 to Ream; see Le, page 1, lines 19-20). The principle product described in Le is a chewing gum for removing or preventing the deposition of plaque on teeth (page 2, lines 26-27; see Examples at pages 12-17). It is the abrasive in the

chewing gum that removes plaque according to Le. The acid in the composition is co-processed with a sugar or sugar alcohol or derivatives thereof, to improve the stability of the acid components. Le generically discloses various products in which the co-processed acid composition can be provided to improve the stability of the acid (page 4, lines 4-11).

2. The Level of Ordinary Skill in the Art

The Examiner's rationale for combining the disparate disclosures of Cherukuri and Le most closely resembles rationale 1 or rationale 7 of the KSR Guidelines. However, the components combined according to the invention do not yield merely predictable results, and one of ordinary skill in the art would not have found a reason to combine the references as suggested by the Examiner to render obvious the invention of independent claims 1, 20, 23 and 24, or any of their respective dependent claims.

In the wake of *KSR*, the Board has emphasized a functional approach to the obviousness determination. Using the words of the *KSR* decision, the Board has looked at “whether the improvement is more than the predictable use of prior art elements *according to their established function.*” *Ex Parte Catan*, 83 U.S.P.Q.2d 1569, 1573 (B.P.A.I. 2007)(quoting *KSR*, emphasis added). In this case, the combination of an oral comfort ingredient and an acidulent in discrete regions is used to obtain a salivation effect. The Examiner has not addressed whether a salivation effect is an obvious result of the combinations she applies. For example the Examiner does not allege that increased oral manipulation of the product in the mouth, as described in claim 24, is an obvious result. Therefore, the Examiner has not stated a rationale that makes the claimed invention obvious.

The Examiner alleges that it would have been obvious to “utilize an acidulent as the bio-effecting agent in the shell portion of Cherukuri’s composition” for two reasons: (1) Cherukuri teaches at col. 7, lines 32-35, that “bio-effecting agents,” such as breath fresheners, breath deodorants and antigingivitis agents can be encapsulated with the bio-adhesive (in the shell portion) of the composition, therefore, the Examiner alleges that one of ordinary skill in the art might have used an acid in that region as an “antigingivitis agent;” alternatively, (2) Le allegedly teaches that “acidulents are conventionally utilized to improve and enhance the release of flavor,” and therefore it allegedly would have been obvious to include acidulent in the flavor-containing region of the product disclosed in Cherukuri (OA, page 4, line 19 to page 5, line 12).

As shown by the Affidavit of Dr. Stephen Moss, submitted May 5, 2008 (Exh. E-3), it is not correct that acids are known to be used as antigingivitis agents. The suitable antigingivitis agents identified in Cherukuri are “chlorhexidine, thymol, menthol, methyl salicylate, eucalyptol and mixtures thereof.” (Cherukuri, col. 7, lines 41-43). None of these are acids. Moreover, reduction of plaque is not recognized as a treatment of gingivitis, and the substitution of an acid taught in Le for a “bio-effecting” agent taught in Cherukuri, on the grounds that an acid is an antigingivitis agent, is not a “reason” to combine the prior art that would be recognized by one of ordinary skill in the art. The Examiner has not alleged a connection between removal of plaque and the treatment of existing gingivitis. Nor is any such connection made in the prior art. These facts, regarding the level of ordinary skill in the art, are attested to in the affidavit of Dr. Moss.

The affidavit of Dr. Moss attests to what one of ordinary skill in the art would glean from the Le reference: that acid is not an antigingivitis agent (See **Exh. E-3**, paragraph 11). Le suggests, at most, that an abrasive chewing gum containing an acid can be used to polish teeth to reduce plaque deposition. (See **Exh. E-3**, paragraph 8). This does not make acid an antigingivitis agent. The Examiner's conclusion that this is a basis for combining Cherukuri and Le does not even rise to the level of a reasonable speculation.

The Examiner has not properly considered the evidence presented by Applicants with respect to the level of ordinary skill in the art. The Examiner has argued that "the Rule 132 Declaration is an opinion Declaration and has been given little weight since it does not provided [*sic*] any factual evidence." (Office Action, page 6). This is not correct. Dr. Moss's Declaration clearly establishes that Dr. Moss is one of greater than ordinary skill in the art of dentistry, that he has reviewed the relevant information, and that in his more than forty years experience in the field has **not** noted that acid had any chemical or physical effect on plaque. (**Exh. E-3**, paragraphs 11-12). His further observation is that one of ordinary skill in the art would **not** have considered acidulent effective to reduce plaque, and would **not** have considered the Le reference to be directed to treatment of prevention of gingivitis. (**Exh. E-3**, paragraph 16).

Respectfully, the Board should consider a declaration of an expert on a fact issue, such as whether acid is an antigingivitis agent, and the failure to do so is reversible error. *In re Alton*, 76 F.3d 1168, 1175; 37 U.S.P.Q. 2d 1578, 1583 (Fed. Cir. 1996), the Examiner mischaracterized a declarant's statement as to what was known in the art, and gave it "little weight" as a mere "opinion affidavit." The Federal Circuit

reversed, as common sense would dictate, given that the level of skill in the art is of critical importance. Similarly in *Ex Parte Tanksley*, 37 U.S.P.Q. 2d 1382; 1994 Pat. App. LEXIS 4 (B.P.A.I. 1994), the Board held that declaration evidence is entitled to fair weight, and held that an Examiner erred in summarily dismissing a declaration as containing “unsupported opinions.”

Apparently, the Examiner considers acid to be an antigingivitis agent and believes that acid could be substituted in a hard candy for that purpose. But the Examiner is not a dentist, and her position is not supported by evidence. To the contrary, Dr. Moss’s affidavit provides factual evidence that acid is not an antigingivitis agent and speaks to what one of ordinary skill in the art would have actually taken from the references.

The second purported rationale for combining Cherukuri and Le is that Le allegedly teaches that acid may be used as a flavor enhancer (OA, page 4, line 19 to page 5, line 12). Therefore (according to the Examiner) acidulent reasonably would be used in the “shell” region that contains a flavor. Again, this is not a reason to arrive at the claimed invention as required by *KSR*. This is not a valid reason to segregate acid and lipid in macroscopic regions, and fails to fully appreciate what the references would fairly suggest to one of ordinary skill in the art. According to Cherukuri, both regions contain flavor. There is no reason to concentrate acid in one region and not the other. According to Le, acid is distributed throughout the product. None of the references applied by the Examiner suggest segregating the acidulent from an oral comfort ingredient. The combination in the manner suggested is based on hindsight, and the Examiner has not provided a reason to arrive at the claimed invention from the prior art. Again, the Office

Action applies the references without regard to the stated functional purpose of the invention, which is a confectionery item useful in the treatment of dry mouth. If the references were relied upon for what they teach about acid, one of ordinary skill in the art would have been led away from the claimed invention and acid would have been provided distributed throughout the product, rather than concentrated in a separate region of the product as claimed.

Accordingly, independent product claims 1, 23 and 24, independent method of treatment claim 20, and the respective dependent claims are not rendered obvious by Cherukuri in view of Le.

3. Method Claim 17

Independent claim 17 is directed to the method of manufacturing the product of the present invention. The Examiner has rejected claim 17 over Cherukuri in view of Le without identifying where Cherukuri or Le discloses (1) mixing an acidulent with a sugar base or a sugarless base, as claimed, and (2) mixing a lipid or surfactant in a sugar base or a sugarless base, and then (3) forming a hard candy from the respective bases. The claimed invention cannot be found obvious absent a showing that these teachings are in the prior art.

D. Claims 18 and 19 Are Not Obvious over Cherukuri, Le and Aldrich

Cherukuri is directed to compressed tablets (see abstract), and Le is primarily directed to products such as toothpaste and chewing gum (see Examples), with only passing reference made to other food products. Aldrich is alleged to show the method of making a hard candy recited in claims 18 and 19 (Office Action, page 9). However, one of ordinary skill in the art, starting from the disclosure of Cherukuri and Le, would have not have been directed to formulate a hard candy according to the method

of Aldrich, using the ingredients of Cherukuri and Le. Accordingly, Aldrich does not overcome the deficiencies of the primary references, and claims 18 and 19 are not obvious in view of this additional reference.

E. Claims 15-16, 21, and 28 Are Not Obvious Over Cherukuri, Le, and Hughes

Claims 15-16, 21 and 28 require the combination of an acidulent and a cooling compound in the salivation region. The Office Action asserts that it would have been obvious to include a cooling compound in the shell region of Cherukuri because (1) Hughes teaches that menthol is both a flavorant and reduces plaque, (2) Le teaches the use of acids to soften plaque on teeth (Office Action page 10). The rejection plainly relies on hindsight. Cherukuri and Le suffer from the deficiencies set forth in section C, supra. Hughes does not remedy the deficiencies. There is no teaching in the references of an acid and cooling compound used together, and even if they were combined there is no disclosure in the prior art of these ingredients being used together in a salivation region.

F. Claims 1-5, 7-8, 13-18, 23, 29, and 31 Are Not Obvious over Bealin-Kelly in View of Hanke

Based on the identified prior art, it would not have been obvious to develop a confectionery product to promote salivation, and a product useful to treat salivation does not result inherently from the combinations proposed by the Examiner.

1. Differences Between the Claimed Invention and the Prior Art

Bealin-Kelly is directed to “center-filled confectionery compositions, especially liquid centre-filled confectionery.” (Bealin-Kelly, col. 1, lines 7-9). The Examiner concedes that Bealin-Kelly “does not exemplify the instant configuration,”

(OA, p. 10). In other words, Bealin-Kelly does not disclose a confectionery product having discrete regions on the exterior of the product.

The Examiner relies on Hanke as teaching this product configuration (meaning the separation of discrete regions on the surface of the product), and notes that Hanke is incorporated by reference into the Bealin-Kelly disclosure (OA, page 11, line 9; Bealin-Kelly, line 18).

The Examiner alleges that the “fill reads on the oral comfort region” (OA, page 10, line 15) and cites Bealin-Kelly col. 5, lines 20-25 as teaching “phospholipids such as lecithin are used in an amount of 0.001-1%,” (Office Action, page 10, lines 9-10).

Bealin-Kelly does not disclose a lipid “selected from the group consisting of partially hydrogenated palm kernel oil, medium chain triglycerides, coconut oil, anhydrous milk fat, cocoa butter, corn oil, palm oil, soybean oil, sunflower oil, canola oil and mixtures thereof,” as set forth in the present claims.

The Examiner’s statement that “Bealin-Kelly teaches an oral comfort region and a salivation region,” (OA, page 12, line 8) is not supported factually. For example, at no point does Bealin-Kelly indicate that an ingredient is present in an amount effective to “lubricate, coat or moisten” the oral cavity, as claimed. At no point does Bealin-Kelly teach or suggest that acidulent in the composition is “effective to aid in the stimulation of the flow of saliva,” as claimed. What the Examiner apparently alleges, is that once a rationale is arrived at to combine these ingredients, then the claimed results must inherently form a treatment for xerostomia.

Notably, both Bealin-Kelly and Hanke are directed to a cough/cold remedy, and do not teach treatment of xerostomia. Moreover, the differences between cough/cold and xerostomia have been amply demonstrated on the record, including in the Declaration of Kevin Stanton, dated May 1, 2006 (**Exh. E-4**), referenced below.

2. Level of Ordinary Skill in the Art

The Board has recognized that

where an examiner has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, the examiner possesses the authority to require an applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. Nevertheless, before an applicant can be put to this burdensome task, the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art. In the case before us, no such evidence or reasoning has been set forward.

Ex Parte Skinner, 2 U.S.P.Q. 2d 1788; 1986 Pat. App LEXIS 4 (B.P.A.I. 1986).

In the present case, the Examiner has not explained the basis for her belief that the combinations she proposes would result in a product that could be used to treat xerostomia, or which would cause increased oral manipulation of the product, etc. This is grounds for reversal under *Ex Parte Skinner*.

Furthermore, the purpose of the product design according to Bealin-Kelly and Hanke is to provide sequential release profiles to the components that are separated in discrete regions (see, for example, Bealin-Kelly Abstract and col. 1, lines 50-52; Hanke, page 3, line 7 and page 11, lines 1-16). This is completely contrary to the result achieved with the claimed invention, in which the oral comfort ingredient soothes the

effect produced by the concentrated acidulent, so that both sensations are in the mouth at about the same time. It is well known that the proposed modification cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose. *In re Gordon*, 733 F.2d 900; 221 U.S.P.Q. 1125 (Fed. Cir. 1984); *In re Ratti*, 270 F.2d 810; 123 U.S.P.Q. 349 (C.C.P.A. 1959). Even the layered configuration of Hanke delivers different release profiles to the ingredients (*i.e.*, sequential release profiles) and does not produce the results of the claimed invention (assuming *arguendo* that the two regions in such a configuration have a surface on the exterior of the product, and assuming *arguendo* that one of ordinary skill in the art would have selected that configuration to begin with). Therefore, it would not have been obvious to arrive at the claimed invention based on the disclosure of either Bealin-Kelly or Hanke, or in view of both of them combined.

Further, the confectionery product according to the claims is not obvious in view of Bealin-Kelly and Hanke because those references are directed to a cough/cold remedy, whereas the claimed invention is directed to a xerostomia treatment, promoting salivation with one region, while moistening, lubricating or coating the mouth with another region. The Declaration of Kevin Stanton, elucidates some of the differences between a cough-cold lozenge, which focuses on treating the throat, and a treatment for dry mouth, which must focus on the mouth. One seeking to produce the claimed invention, a product to increase salivation and treat dry mouth, would not have looked to prior art relating to throat lozenges.

Thus, if the references were relied upon for what they actually suggested to one of ordinary skill in the art, they would lead one away from the claimed invention,

toward a result in which the flavors in the product are released sequentially and toward a product for soothing the throat. This would not yield the functional results described and claimed, wherein one region of the confectionery promotes salivation at the same time another region soothes the mouth.

Accordingly, independent product claims 1 and 23, and method of manufacturing claim 17 are not rendered obvious by Bealin-Kelly in view of Hanke. Moreover, the claims dependent thereon are also not rendered obvious by the same art.

G. Claims 20 and 21 Are Not Obvious Over
Bealin-Kelly, Hanke and National Institute of Dental
and Craniofacial Research, NIH Publication, June 1999

Claims 20 and 21 are directed to a method of treating xerostomia, which involves treating the mouth with the product described in the foregoing. The Examiner alleges that the treatment would have been obvious because it was known that sucking on a hard candy (any hard candy) would provide relief from dry mouth. However, the argument does not motivate the treatment of xerostomia with the claimed product.

It was known in the prior art that sucking on a lozenge might provide some relief from xerostomia (see the specification at page 2, lines 23-29). The NIH publication (which was first cited by the Appellants to demonstrate to the Examiner that dry mouth is, in fact, a recognized indication that can be distinguished from throat irritation generally), simply reflects what is stated in the specification. However, the Background of the Invention also makes clear that a need existed in the art for more effective products specifically adapted to the treatment of xerostomia. The claimed invention is a treatment of xerostomia using a confectionery product having a specified configuration, and the nonobviousness of that invention has not been addressed in the

rejection. Stated differently, the claimed product is novel and non-obvious for the reasons given above, and its use to treat dry mouth is likewise non-obvious.

To demonstrate that the present invention provides a treatment for xerostomia that can be distinguished from the relief provided by sucking on a generic candy, Appellants previously provided marketing data and analysis in the form of a Declaration by Donald Mayer (**Exh. E-5**). It is believed that consumer reaction to the product registered an unusual awareness on the part of consumers of the product functionality as a treatment of dry mouth, as opposed to merely registering consumer satisfaction, for example (see **Exh. E-5**, paragraphs 10-11). These remarks and accompanying analysis are evidence that the claimed treatment of xerostomia is distinguishable from and nonobvious over the relief that might have been provided by sucking on a generic candy. Claims 20-21, directed to the method of treatment, should be allowed for these additional reasons.

H. Claim 19 is Not Obvious over Bealin-Kelly, Hanke and Klacik

Klacik is not believed to overcome the deficiencies of Bealin-Kelly and Hanke and therefore Claim 19 should be allowable for the same reasons as argued above in connection with the independent method claim 17. Klacik is applied against the claims as it relates to the mold configuration used in the method of making. One would only utilize a mold according to Klacik if one had just decided on a configuration (such as in Klacik) where discrete regions are present on the surface of the product. As noted above, the layered and center-filled configurations of Hanke and Bealin-Kelly are designed to obtain sequential release profiles, so that one of ordinary skill in the art would have had no reason to arrive at that configuration, and the use of the mold described in Klacik would not have been obvious.

CONCLUSION

It is respectfully submitted that the final rejection of the claims should be reversed for the reasons stated.

Respectfully submitted,

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VIII. Claims Appendix

1. (Previously presented) A confectionery product comprising:

(i) a salivation region comprising an acidulent in an amount effective to aid in the stimulation of the flow of saliva in an oral cavity and a salivation region confectionery base that is a sugar base or a sugarless base; and

(ii) an oral comfort region comprising an oral comfort ingredient selected from the group consisting of lipids, surfactants and mixtures thereof in an amount effective to lubricate, coat or moisten said oral cavity and an oral comfort region confectionery base that is a sugar base or a sugarless base, wherein the lipid is selected from the group consisting of partially hydrogenated palm kernel oil, medium chain triglycerides, coconut oil, anhydrous milk fat, cocoa butter, corn oil, palm oil, soybean oil, sunflower oil, canola oil and mixtures thereof,

wherein the salivation region and the oral comfort region each have a surface on the exterior of the product,

wherein the acidulent is not uniformly distributed throughout the product but is concentrated in the salivation region, and the oral comfort ingredient is concentrated in the oral comfort region,

wherein the confectionery product is a hard candy, and

wherein the confectionery product comprises about 50 to about 99.5 percent by weight confectionery base.

2. (Original) The confectionery product according to claim 1, wherein said salivation region confectionery base and said oral comfort region confectionery base are sugar bases.

3. (Original) The confectionery product according to claim 2, wherein said sugar bases comprises a sugar selected from the group consisting of sucrose, glucose, fructose, maltose, corn syrup and mixtures thereof.

4. (Original) The confectionery product according to claim 1, wherein said salivation region confectionery base and said oral comfort region confectionery base are sugarless bases.

5. (Previously Presented) The confectionery product according to claim 4, wherein said sugarless bases are selected from the group consisting of isomalt, erythritol, hydrogenated starch hydrolysates, sorbitol, xylitol, mannitol and mixtures thereof.

6. (Cancelled).

7. (Previously presented) A confectionery product according to claim 1, wherein said acidulent is selected from the group consisting of citric acid, malic acid, succinic acid, adipic acid and mixtures thereof.

8. (Previously presented) The confectionery product according to claim 1, wherein said acidulent is present in an amount from about 0.01% to about 4% by weight of the confectionery product.

9. (Cancelled).

10. (Previously Presented) The confectionery product according to claim 1, wherein said oral comfort ingredient is a lipid.

11. (Original) A confectionery product according to claim 10, wherein said lipid is present in an amount of about 1 to about 20% by weight of the confectionery product.

12. (Cancelled).

13. (Previously presented) The confectionery product according to claim 1, wherein said oral comfort region comprises a surfactant selected from the group consisting of nonionic surfactants, anionic surfactants and amphoteric surfactants.

14. (Original) The confectionery product according to claim 13, wherein said surfactant is present in an amount of about 0.5 percent to about 4 percent by weight of said oral comfort region.

15. (Original) The confectionery product according to claim 1, wherein said salivation region comprises an acidulent and a cooling compound.

16. (Original) The confectionery product according to claim 15, wherein said cooling compound is present in an amount of about 0.01 to 0.2 % by weight of the confectionery product.

17. (Previously presented) A method of preparing a hard candy confectionery product having a salivation region and an oral comfort region that is separate and distinct from said salivation region, said method comprising the steps of:

(i) mixing an acidulent with a salivation region confectionery base that is a sugar base or a sugarless base to form a salivation agent containing confectionery base;

(ii) mixing an oral comfort ingredient selected from the group consisting of lipids, surfactants and mixtures thereof with an oral comfort region confectionery base that is a sugar base or a sugarless base to form an oral comfort ingredient containing confectionery base, wherein the lipid is selected from the group consisting of partially hydrogenated palm kernel oil, medium chain triglycerides, coconut oil, anhydrous milk fat, cocoa butter, corn oil, palm oil, soybean oil, sunflower oil, canola oil and mixtures thereof; and

(iii) forming said hard candy confectionery product with said salivation agent containing confectionery base and said oral comfort ingredient containing confectionery base in a manner that maintains said salivation agent containing confectionery base and said oral comfort ingredient containing confectionery base in separate and distinct regions of said confectionery product,

wherein the salivation region and the oral comfort region each have a surface on the exterior of the product, and

wherein the product comprises about 50 to about 99.5 percent by weight confectionery base.

18. (Previously presented) The method according to claim 17, wherein said step of forming comprises substantially simultaneously depositing said acidulent containing confectionery base and said oral comfort ingredient containing confectionery base in separate and distinct regions of a confectionery mold.

19. (Original) The method according to claim 18, wherein said confectionery mold has a raised ridge running along its bottom inner surface that defines said separate and distinct regions of said confectionery mold.

20. (Previously presented) A method for treating xerostomia, which comprises:

introducing into the oral cavity a hard candy confectionery product containing:

an acidulent concentrated in a salivation region of said product in a salivation agent confectionery base which is a sugar base or a sugarless base, and

an oral comfort ingredient, selected from the group consisting of lipids, surfactants and mixtures thereof, concentrated in an oral comfort region of said product in an oral comfort ingredient confectionery base which is a sugar base or a sugarless base, wherein the lipid is selected from the group consisting of partially hydrogenated palm kernel oil, medium chain triglycerides, coconut oil, anhydrous milk fat, cocoa butter, corn oil, palm oil, soybean oil, sunflower oil, canola oil and mixtures thereof,

wherein said salivation region and said oral comfort region each have a surface on the exterior of the product, and

wherein the hard candy confectionery product comprises about 50 to about 99.5 percent by weight confectionery base.

21. (Previously presented) A method according to claim 20, wherein said salivation region comprises the acidulent in combination with a cooling compound.

22. (Cancelled).

23. (Previously presented) A hard candy confectionery product comprising:

(i) a salivation region comprising (a) an acidulent in an amount effective to aid in the stimulation of the flow of saliva in an oral cavity and (b) a salivation region confectionery base selected from either (1) the group consisting of sucrose, glucose, fructose, maltose, corn syrup, and mixtures thereof, or (2) the group consisting of isomalt, erythritol, hydrogenated starch hydrolysates, sorbitol, xylitol, mannitol and mixtures thereof; and

(ii) an oral comfort region comprising (c) an oral comfort ingredient selected from the group consisting of lipids, surfactants and mixtures thereof in an amount effective to lubricate, coat or moisten said oral cavity, wherein the lipid is selected from the group consisting of partially hydrogenated palm kernel oil, medium chain triglycerides, coconut oil, anhydrous milk fat, cocoa butter, corn oil, palm oil, soybean oil, sunflower oil, canola oil and mixtures thereof, and (d) an oral comfort region confectionery base selected from either (1) the group consisting of sucrose, glucose, fructose, maltose, corn syrup, and mixtures thereof, or (2) the group consisting of isomalt,

erythritol, hydrogenated starch hydrolysates, sorbitol, xylitol, mannitol and mixtures thereof,

wherein the salivation region and the oral comfort region each have a surface on the exterior of the product,

wherein the acidulent is not uniformly distributed throughout the product but is concentrated in the salivation region, and

wherein the oral comfort ingredient is concentrated in the oral comfort region.

24. (Previously presented) A confectionery product comprising:

(i) a salivation region comprising an acidulent in an amount effective to aid in the stimulation of the flow of saliva in an oral cavity and a salivation region confectionery base which is a sugarless base or a sugar base; and

(ii) an oral comfort region comprising an oral comfort ingredient selected from the group consisting of partially hydrogenated palm kernel oil, medium chain triglycerides, coconut oil, anhydrous milk fat, cocoa butter, corn oil, palm oil, soybean oil, sunflower oil, canola oil and mixtures thereof in an amount effective to lubricate, coat or moisten said oral cavity and an oral comfort region confectionery base which is a sugarless base or a sugar base,

wherein the salivation region and the oral comfort region each have a surface on the exterior of the product,

wherein the acidulent is not uniformly distributed throughout the product but is concentrated in the salivation region to cause movement of the product in the oral cavity, and the oral comfort ingredient is concentrated in the oral comfort region,

wherein about 50 to about 99.5 percent by weight of the product is confectionery base, and

wherein the confectionery is a hard candy.

25.-27. (Cancelled).

28. (Previously presented) The confectionery product of claim 24, wherein the salivation region contains an acidulent and a cooling compound.

29. (Previously presented) The confectionery product of claim 1, comprising a single salivation agent region that borders, but is separate from, a single oral comfort region.

30. (Previously presented) The confectionery product of claim 24, comprising a single salivation agent region that borders, but is separate from, a single oral comfort region.

31. (Previously presented) The confectionery product of claim 1, wherein the concentration of acidulent in the salivation region results in enhanced oral manipulation of the product.

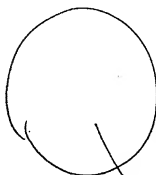
32. (Previously presented) The confectionery product of claim 24, wherein the concentration of acidulent in the salivation region results in enhanced oral manipulation of the product.

IX. Evidence Appendix

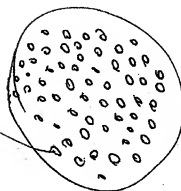
- E-1 Graphic submitted for Examiner Interview, December 16, 2002
- E-2 Federal Register, Vol. 72, No. 195, October 10, 2007 (“KSR Guidelines”)
- E-3 Declaration of Stephen J. Moss
- E-4 Declaration of Kevin Stanton
- E-5 Declaration of Donald L. Mayer

APPENDIX E1

SAME OVERALL CONCENTRATION:

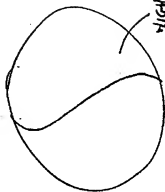


UNIFORM CONC.
THROUGHOUT



HIGH CONCENTRATION

WO '427 OR MICROENCAPSULATION



HIGH
CONCENTR.
"INVENTIVE"

THESE HAVE SUBSTANTIALLY THE
SAME OVERALL TASTE EFFECT:
"TANGY" → when evenly
dispersed.

HIGH CONCENTRATION
REGION HAS "RELATINO"
EFFECT, CAUSES MECHANICAL
ACTION OF THE PIECE
IN THE MOUTH

TO: EYE GOLLAMDI

09/825992

APPENDIX E2

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (see ADDRESSES) at least 5 days prior to the meeting date.

Dated: October 3, 2007.

Tracy L. Thompson,
Acting Director, Office of Sustainable
Fisheries, National Marine Fisheries Service.
[FR Doc. E7-19823 Filed 10-9-07; 8:45 am]
BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE**Patent and Trademark Office**

[Docket No.: PTO-P-2007-0031]

**Examination Guidelines for
Determining Obviousness Under 35
U.S.C. 103 in View of the Supreme
Court Decision in *KSR International
Co. v. Teleflex Inc.***

AGENCY: United States Patent and
Trademark Office, Commerce.
ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) is publishing examination guidelines for determining obviousness under 35 U.S.C. 103 in view of the Supreme Court decision in *KSR International Co. v. Teleflex Inc.* These guidelines will assist USPTO personnel to make a proper determination of obviousness under 35 U.S.C. 103 and to provide an appropriate supporting rationale.
DATES: These guidelines are effective October 10, 2007.

FOR FURTHER INFORMATION CONTACT: Contact either Kathleen Kahler Fonda, Legal Advisor (telephone (571) 272-7754; e-mail kathleen.fonda@uspto.gov) or Pinchus M. Laufer, Patent Examination Policy Analyst (telephone (571) 272-7726; e-mail pinchus.laufer@uspto.gov), of the Office of the Deputy Commissioner for Patent Examination Policy. Alternatively, mail may be addressed to Ms. Fonda or Mr. Laufer at Commissioner for Patents, attn: KSR, P.O. Box 1450, Alexandria, VA 22313-1450.

SUPPLEMENTARY INFORMATION: These guidelines are intended to assist Office personnel to make a proper determination of obviousness under 35 U.S.C. 103, and to provide an appropriate supporting rationale in view of the recent decision by the Supreme Court in *KSR International Co. v. Teleflex Inc.* (KSR).¹ The guidelines are

based on the Office's current understanding of the law, and are believed to be fully consistent with the binding precedent of the Supreme Court.²

These guidelines do not constitute substantive rule making and hence do not have the force and effect of law. They have been developed as a matter of internal Office management and are not intended to create any right or benefit, substantive or procedural, enforceable by any party against the Office. Rejections will continue to be based upon the substantive law, and it is these rejections that are appealable. Consequently, any failure by Office personnel to follow the guidelines is neither appealable nor petitionable.

To the extent that earlier guidance from the Office, including certain sections of the current Manual of Patent Examining Procedure (MPEP), is inconsistent with the guidance set forth herein, Office personnel are to follow these guidelines. The next revision of the MPEP will be updated accordingly.

I. The *KSR* Decision and Principles of the Law of Obviousness

Teleflex owned a patent claiming technology useful in the gas pedal of a car. The invention at issue in *KSR* was a pedal assembly that could be adjusted to accommodate drivers of different statures. The electronic pedal-position sensor was positioned on the support for the pedal assembly, and the pivot point of the pedal remained fixed regardless of how the pedal assembly was adjusted. This combination of the fixed pivot point for the adjustable pedal and the fixed sensor position on the support resulted in a simpler, lighter, and more compact design.

Teleflex sued KSR for infringement. The district court cited references that separately taught adjustable pedals and sensors, and found on summary judgment that Teleflex's patent was invalid for obviousness. On appeal, the Federal Circuit vacated the district court's decision, and remanded the case. The Federal Circuit stated that "the district court's analysis applied an incomplete teaching-suggestion-motivation test" in arriving at the finding of obviousness.³

Upon KSR's petition for review of the Federal Circuit's decision, the Supreme Court reversed, concluding that the district court had correctly determined that the patent was invalid for

obviousness. The Supreme Court reaffirmed the familiar framework for determining obviousness as set forth in *Graham v. John Deere Co.*, but stated that the Federal Circuit had erred by applying the teaching-suggestion-motivation (TSM) test in an overly rigid and formalistic way.⁴ Specifically, the Supreme Court stated that the Federal Circuit had erred in four ways: (1) "By holding that courts and patent examiners should look only to the problem the patentee was trying to solve;"⁵ (2) by assuming "that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem;"⁶ (3) by concluding "that a patent claim cannot be proved obvious merely by showing that the combination of elements was 'obvious to try';"⁷ and (4) by overemphasizing "the risk of courts and patent examiners falling prey to hindsight bias" and as a result applying "[r]igid preventative rules that deny factfinders recourse to common sense."⁸

In *KSR*, the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art,"⁹ and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."¹⁰ The Supreme Court stated that there are "[t]hree cases decided after *Graham* [that] illustrate this doctrine."¹¹ (1) In *United States v. Adams*, * * * "[t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result."¹² (2) In *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, * * * "[t]he two [pre-existing elements] in combination did no more than they would in separate, sequential operation."¹³ (3) [I]n *Sakraid v. AG Pro, Inc.*, the Court derived * * * the conclusion that when

¹ KSR, 550 U.S. at ___, 82 USPQ2d at 1391.

² *Id.* at ___, 82 USPQ2d at 1397.

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹ 550 U.S. ___, 82 USPQ2d 1385 (2007).

² Further developments in the law of obviousness are to be expected in view of *KSR*. Thus, it is not clear which Federal Circuit decisions will retain their viability.

³ *Teleflex Inc. v. KSR Int'l Co.*, 119 Fed. Appx. 282, 286 (Fed. Cir. 2005).

a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious."¹⁴ (Internal quotations omitted.) The principles underlying these cases are instructive when the question is whether a patent application claiming the combination of elements of prior art would have been obvious. The Supreme Court further stated that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, 35 U.S.C. 103 bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.¹⁵

When considering obviousness of a combination of known elements, the operative question is thus "whether the improvement is more than the predictable use of prior art elements according to their established functions."¹⁶

II. The Basic Factual Inquiries of *Graham v. John Deere Co.*

An invention that would have been obvious to a person of ordinary skill at the time of the invention is not patentable.¹⁷ As reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*¹⁸ Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (1) Determining the scope and content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art; and
- (3) Resolving the level of ordinary skill in the pertinent art.

Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel.¹⁹ Such evidence, sometimes referred to as "secondary considerations," may include evidence of commercial success, long-felt but unsolved needs, failure of others, and unexpected results. The evidence may be included in the specification as filed,

accompany the application on filing, or be provided in a timely manner at some other point during the prosecution. The weight to be given any objective evidence is decided on a case-by-case basis. The mere fact that an applicant has presented evidence does not mean that the evidence is dispositive of the issue of obviousness.

The question of obviousness must be resolved on the basis of these factual determinations. While each case is different and must be decided on its own facts, the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis.²⁰ As stated by the Supreme Court in *KSR*, "While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls."²¹

Office Personnel as Factfinders

Office personnel fulfill the critical role of factfinder when resolving the *Graham* inquiries. It must be remembered that while the ultimate determination of obviousness is a legal conclusion, the underlying *Graham* inquiries are factual. When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.

Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. 103. 35 U.S.C. 132 requires that the applicant be notified of the reasons for the rejection of the claim so that he or she can decide how best to proceed. Clearly setting forth findings of fact and the rationale(s) to support a rejection in an Office action leads to the prompt

resolution of issues pertinent to patentability.²²

In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge. This is so regardless of whether the source of that knowledge and ability was documentary prior art, general knowledge in the art, or common sense. What follows is a discussion of the *Graham* factual inquiries.

A. Determining the Scope and Content of the Prior Art

In determining the scope and content of the prior art, Office personnel must first obtain a thorough understanding of the invention disclosed and claimed in the application under examination by reading the specification, including the claims, to understand what the applicant has invented.²³ The scope of the claimed invention must be clearly determined by giving the claims the "broadest reasonable interpretation consistent with the specification."²⁴ Once the scope of the claimed invention is determined, Office personnel must then determine what to search for and where to search.

1. *What to search for:* The search should cover the claimed subject matter and should also cover the disclosed features which might reasonably be expected to be claimed.²⁵ Although a rejection need not be based on a teaching or suggestion to combine, a preferred search will be directed to finding references that provide such a teaching or suggestion if they exist.

2. *Where to search:* Office personnel should continue to follow the general search guidelines set forth in MPEP § 904 to § 904.03 regarding search of the prior art. Office personnel are reminded that, for purposes of 35 U.S.C. 103, prior art can be either in the field of applicant's endeavor or be reasonably pertinent to the particular problem with which the applicant was concerned. Furthermore, prior art that is in a field of endeavor other than that of the applicant,²⁶ or solves a problem which

¹⁴ *Id.* at ___, 82 USPQ2d at 1398-99.

¹⁵ *Id.* at ___, 82 USPQ2d at 1398.

¹⁶ *Id.*

¹⁷ 35 U.S.C. 103(a).

¹⁸ 383 U.S. 1, 146 USPQ 459 (1966).

¹⁹ *Id.* at 17-18, 146 USPQ at 467.

²⁰ The *Graham* factors were reaffirmed and relied upon by the Supreme Court in its consideration and determination of obviousness in the fact situation presented in *KSR*, 550 U.S. at ___, 82 USPQ2d at 1391. The Supreme Court has utilized the *Graham* factors in each of its obviousness decisions since 1980. See *Schmidhauser v. Ag Pro, Inc.*, 425 U.S. 273, 169 USPQ 449, reh'g denied, 426 U.S. 955 (1978); *Dunn v. Johnston*, 425 U.S. 219, 169 USPQ 257 (1978); and *Anderson v. Black Rock, Inc. v. Foremost Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969).

²¹ *KSR*, 550 U.S. at ___, 82 USPQ2d at 1391.

²² These guidelines focus on the proper content of an obviousness rejection, and should not be construed as dictating any particular format.

²³ See MPEP § 904 (8th edition, revision 5, August 2006).

²⁴ See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316, 78 USPQ2d 1321, 1329 (Fed. Cir. 2006) and MPEP § 2111.

²⁵ See MPEP § 904.02.

²⁶ As noted by the Court in *KSR*, "[w]hen a work is available in one field of endeavor, design

is different from that which the applicant was trying to solve, may also be considered for the purposes of 35 U.S.C. 103.²⁷

For a discussion of what constitutes prior art, see MPEP § 901 to § 901.06(d) and § 2121 to § 2129.

B. Ascertaining the Differences Between the Claimed Invention and the Prior Art

Ascertaining the differences between the claimed invention and the prior art requires interpreting the claim language,²⁸ and considering both the invention and the prior art as a whole.²⁹

C. Resolving the Level of Ordinary Skill in the Art

Any obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill. A finding as to the level of ordinary skill may be used as a partial basis for a resolution of the issue of obviousness.

The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. Factors that may be considered in determining the level of ordinary skill in the art may include: (1) "Type of problems encountered in the art;" (2) "prior art solutions to those problems;" (3) "rapidity with which innovations are made;" (4) "sophistication of the technology;" and (5) "educational level of active workers in the field. In a given case, every factor may not be present,

and one or more factors may predominate."³⁰

"A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton."³¹ "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle."³² Office personnel may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ."³³

In addition to the factors above, Office personnel may rely on their own technical expertise to describe the knowledge and skills of a person of ordinary skill in the art.³⁴

III. Rationales To Support Rejections Under 35 U.S.C. 103

Once the *Graham* factual inquiries are resolved, Office personnel must determine whether the claimed invention would have been obvious to one of ordinary skill in the art.

The obviousness analysis cannot be confined by * * * overemphasis on the importance of published articles and the explicit content of issued patents * * *. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends.³⁵

Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations; however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. The "mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness."³⁶ The gap between the prior art and the claimed invention may not be "so great as to render the

[claim] nonobvious to one reasonably skilled in the art."³⁷ In determining obviousness, neither the particular motivation to make the claimed invention nor the problem the inventor is solving controls. The proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts.³⁸ Factors other than the disclosures of the cited prior art may provide a basis for concluding that it would have been obvious to one of ordinary skill in the art to bridge the gap. The rationales discussed below outline reasoning that may be applied to find obviousness in such cases.

If the search of the prior art and the resolution of the *Graham* factual inquiries reveal that an obviousness rejection may be made using the familiar teaching-suggestion-motivation (TSM) rationale, then such a rejection using the TSM rationale can still be made. Although the Supreme Court in *KSR* cautioned against an overly rigid application of TSM, it also recognized that TSM was one of a number of valid rationales that could be used to determine obviousness.³⁹ Office personnel should also consider whether one or more of the other rationales set forth below support a conclusion of obviousness.⁴⁰ Note that the list of rationales provided below is not intended to be an all-inclusive list. Other rationales to support a conclusion of obviousness may be relied upon by Office personnel.

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*⁴¹ stated that "[r]ejections on obviousness cannot be sustained by

incentives and other market forces can prompt variations of it, either in the same field or a different one." (Emphasis added) 550 U.S. at 82 USPQ2d at 1395.

²⁷ The Court in *KSR* stated that "[t]he first error * * * in this case was * * * holding that courts and patent examiners should look only to the problem the patentee was trying to solve. The Court of Appeals failed to recognize that the problem motivating the patentee may be only one of many addressed by the patent's subject matter." * * *. The second error (was) * * * "that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem." 550 U.S. at 82 USPQ2d at 1397. Federal Circuit case law prior to the Supreme Court's decision in *KSR* is generally in accord with these statements by the *KSR* Court. See, e.g., *In re Dillon*, 919 F.2d 688, 693, 18 USPQ2d 1897, 1901 (Fed. Cir. 1990) (en banc) ("It is not necessary in order to establish a *prima facie* case of obviousness that both a structural similarity between a claimed and prior art compound (or a key component of a composition) be shown and that there be a suggestion in or expectation from the prior art that the claimed compound or composition will have the same or a similar utility as one newly discovered by applicant."); *In re Linde*, 458 F.2d 1013, 1018, 173 USPQ 560, 562 (CCPA 1972) ("The fact that [applicant] uses sugar for a different purpose does not alter the conclusion that its use in a prior art composition would be *prima facie* obvious from the purpose disclosed in the references.")

²⁸ See MPEP § 2111.

²⁹ See MPEP § 2141.02.

³⁰ *In re GPAC*, 37 F.3d 1573, 1579, 35 USPQ2d 1116, 1121 (Fed. Cir. 1994) *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986); *Envil Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696, 218 USPQ 865, 868 (Fed. Cir. 1983).

³¹ *KSR*, 550 U.S. at 82 USPQ2d at 1397.

³² *Id.*

³³ *Id.* at 82 USPQ2d at 1396.

³⁴ The Federal Circuit has stated that examiners and administrative patent judges on the Board are "persons of scientific competence in the fields in which they work" and that their findings are "informed by their scientific knowledge, as to the meaning of prior art references to persons of ordinary skill in the art." *In re Berg*, 320 F.3d 1310, 1315, 65 USPQ2d 2003, 2007 (Fed. Cir. 2003).

³⁵ *KSR*, 550 U.S. at 82 USPQ2d at 1396.

³⁶ *Dann v. Johnston*, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976).

³⁷ *Id.*

³⁸ 35 U.S.C. 103(a).

³⁹ According to the Supreme Court, establishment of the TSM approach to the question of obviousness "captured a helpful insight." 550 U.S. at 82 USPQ2d 1385, 1396 (citing *In re Bergel*, 292 F.2d 955, 959-67, 130 USPQ 295, 297-08 (1961)). Furthermore, the Court explained that "(t)here is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis." *KSR*, 550 U.S. at 82 USPQ2d at 1396. The Supreme Court also commented that the Federal Circuit "no doubt has applied the test in accord with these principles (as forth in *KSR*) in many cases." *Id.* at 82 USPQ2d at 1396.

⁴⁰ The Court in *KSR* identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham*. *Id.* at 82 USPQ2d at 1395-97.

⁴¹ 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."⁴²

Rationales

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results;

(C) Use of known technique to improve similar devices (methods, or products) in the same way;

(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(E) "Obvious to try"—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

The subsections below include discussions of each rationale along with examples illustrating how the cited rationales may be used to support a finding of obviousness. The cases cited (from which the facts were derived) may not necessarily stand for the proposition that the particular rationale is the basis for the court's holding of obviousness. Note that, in some instances, a single case is used in different subsections to illustrate the use of more than one rationale to support a finding of obviousness. It may often be the case that, once the *Graham* inquiries have been satisfactorily resolved, a conclusion of obviousness may be supported by more than one line of reasoning.

A. Combining Prior Art Elements According to Known Methods To Yield Predictable Results

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Office personnel must then articulate the following:

(1) a finding that the prior art included each element claimed, although not

necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;

(2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately;

(3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and

(4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention.⁴³ "[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."⁴⁴ If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1: The claimed invention in *Anderson's Black Rock, Inc. v. Pavement Salvage Co.*⁴⁵ was a paving machine which combined several well-known elements onto a single chassis. Standard prior art paving machines typically combined equipment for spreading and shaping asphalt onto a single chassis. The patent claim included the well-known element of a radiant-heat burner attached to the side of the paver for the purpose of preventing cold joints during continuous strip paving.⁴⁶ All of the component parts were known in the prior art. The only difference was the combination of the "old elements" into a single device by mounting them on a single chassis. The Court found that the operation of the heater was in no way dependent on the operation of the other equipment, and that a separate heater could also be used in conjunction with a

standard paving machine to achieve the same results. The Court concluded that "[t]he convenience of putting the burner together with the other elements in one machine, though perhaps a matter of great convenience, did not produce a 'new' or 'different function'."⁴⁷ And that those skilled in the art the use of the old elements in combination would have been obvious.

Note that combining known prior art elements is not sufficient to render the claimed invention obvious if the results would not have been predictable to one of ordinary skill in the art.⁴⁸ "When the prior art teaches away from combining certain known elements, discovery of successful means of combining them is more likely to be nonobvious."⁴⁹

Example 2: The claimed invention in *Ruiz v. AB Chocoma Co.*⁵⁰ was directed to a system which employs a screw anchor for underpinning existing foundations and a metal bracket to transfer the building load onto the screw anchor. The prior art (Fuller) used screw anchors for underpinning existing structural foundations. Fuller used a concrete haunch to transfer the load of the foundation to the screw anchor. The prior art (Gregory) used a push pier to underpin existing structural foundations. Gregory taught a method of transferring load using a bracket, specifically, a metal bracket transfers the foundation load to the push pier. The pier is driven into the ground to support the load. Neither reference showed the two elements of the claimed invention—screw anchor and metal bracket—used together. The court found that "artisans knew that a foundation underpinning system requires a means of connecting the foundation to the load-bearing member."⁵¹

The nature of the problem to be solved—underpinning unstable foundations—as well as the need to connect the member to the foundation to accomplish this goal, would have led one of ordinary skill in the art to choose an appropriate load bearing member and a compatible attachment. Therefore, it would have been obvious to use a metal bracket (as shown in Gregory) in combination with the screw anchor (as

⁴² *Id.* at 60, 163 USPQ at 874.

⁴³ *United States v. Adams*, 383 U.S. 39, 51–52, 148 USPQ 479, 483 (1966). In *Adams*, the claimed invention was to a battery with one magnesium electrode and one cuprous chloride electrode that could be stored dry and activated by the addition of plain water or salt water. Although magnesium and cuprous chloride were individually known battery components, the Court concluded that the claimed battery was nonobvious. The Court stated that "[c]onsidering the fact that each of the elements of the Adams battery was well known in the prior art, to combine them as did Adams required that a person reasonably skilled in the prior art must 'ignore' the teaching away of the prior art that such batteries were impractical and that water-activated batteries were successful only when combined with electrolytes detrimental to the use of magnesium electrodes. *Id.* at 42–43, 50–52, 148 USPQ at 480, 483.

⁴⁴ *KSR*, 550 U.S. at ___, 82 USPQ2d at 1395.

⁴⁵ 357 F.2d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004).

⁴⁶ *Id.* at 1276, 69 USPQ2d at 1691.

⁴⁷ *Id.* at ___, 82 USPQ2d at 1395; *Sakaida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson's Black Rock, Inc. v. Pavement Salvage Co.*, 383 U.S. 37, 52–53, 148 USPQ 473, 475 (1966); *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

⁴⁸ *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

⁴⁹ 396 U.S. 57, 163 USPQ 873 (1969).

⁵⁰ The prior art used radiant heat for softening the asphalt to make patches, but did not use radiant heat burners to achieve continuous strip paving.

⁴² *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

shown in Fuller) to underpin unstable foundations.

B. Simple Substitution of One Known Element for Another To Obtain Predictable Results

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Office personnel must then articulate the following:

- (1) a finding that the prior art contained a device (method, product, etc.) which differed from the claimed device by the substitution of some components (step, element, etc.) with other components;
- (2) a finding that the substituted components and their functions were known in the art;
- (3) a finding that one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1: The claimed invention in *In re Fout*⁵² was directed to a method for decaffeinating coffee or tea. The prior art (Pagliaro) method produced a decaffeinated vegetable material and trapped the caffeine in a fatty material (such as oil). The caffeine was then removed from the fatty material by an aqueous extraction process. Applicant (Fout) substituted an evaporative distillation step for the aqueous extraction step. The prior art (Waterman) suspended coffee in oil and then directly distilled the caffeine through the oil. The court found that "[b]ecause both Pagliaro and Waterman teach a method for separating caffeine from oil, it would have been *prima facie* obvious to substitute one method for the other. Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious."⁵³

Example 2: The invention in *In re O'Farrell*⁵⁴ was directed to a method for synthesizing a protein in a transformed bacterial host species by substituting a heterologous gene for a gene native to the host species. Generally speaking, protein synthesis *in vivo* follows the path of DNA to RNA to protein. Although the prior art

Polisky article (authored by two of the three inventors of the application) had explicitly suggested employing the method described for protein synthesis, the inserted heterologous gene exemplified in the article was one that normally did not proceed all the way to the protein production step, but instead terminated with the RNA. A second reference to Bahl had described a general method of inserting chemically synthesized DNA into a plasmid. Thus, it would have been obvious to one of ordinary skill in the art to replace the prior art gene with another gene known to lead to protein production, because one of ordinary skill in the art would have been able to carry out such a substitution, and the results were reasonably predictable.

In response to applicant's argument that there had been significant unpredictability in the field of molecular biology at the time of the invention, the court stated that the level of skill was quite high and that the teachings of Polisky, even taken alone, contained detailed enabling methodology and included the suggestion that the modification would be successful for synthesis of proteins.

This is not a situation where the rejection is a statement that it would have been "obvious to try" without more. Here there was a reasonable expectation of success. "Obviousness does not require absolute predictability of success."⁵⁵

Example 3: The fact pattern in *Ruiz v. AB Chance Co.*⁵⁶ is set forth above in Example 2 in subsection III.A.

The prior art showed differing load-bearing members and differing means of attaching the foundation to the member. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the metal bracket taught in Gregory for Fuller's concrete haunch for the predictable result of transferring the load.

Example 4: The claimed invention in *Ex parte Smith*⁵⁷ was a pocket insert for a bound book made by gluing a base sheet and a pocket sheet of paper together to form a continuous two-ply seam defining a closed pocket. The prior art (Wyant) disclosed at least one pocket formed by folding a single sheet and securing the folded portions along the inside margins using any convenient bonding method. The prior art (Wyant) did not disclose bonding the sheets to form a continuous two-ply seam. The prior art (Dick) disclosed a pocket that is made by stitching or otherwise securing two sheets along three of its four edges to define a closed pocket with an opening along its fourth edge.

In considering the teachings of Wyant and Dick, the Board "found that (1) each of the claimed elements was within

the scope and content of the prior art: (2) one of ordinary skill in the art could have combined the elements as claimed by methods known at the time the invention was made; and (3) one of ordinary skill in the art would have recognized at the time the invention was made that the capabilities or functions of the combination were predictable." Citing *KSR*, the Board concluded that "[t]he substitution of the continuous, two-ply seam of Dick for the folded seam of Wyant thus is no more than 'the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.'"

C. Use of Known Technique To Improve Similar Devices (Methods, or Products) in the Same Way

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Office personnel must then articulate the following:

- (1) a finding that the prior art contained a "base" device (method, or product) upon which the claimed invention can be seen as an "improvement";
- (2) a finding that the prior art contained a "comparable" device (method, or product) that is not the same as the base device) that was improved in the same way as the claimed invention;
- (3) a finding that one of ordinary skill in the art could have applied the known "improvement" technique in the same way to the "base" device (method, or product) and the results would have been predictable to one of ordinary skill in the art; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that a method of enhancing a particular class of devices (methods, or products) was made part of the ordinary capabilities of one skilled in the art based upon the teaching of such improvement in other situations. One of ordinary skill in the art would have been capable of applying this known method of enhancement to a "base" device (method, or product) in the prior art and the results would have been predictable to one of ordinary skill in the art. The Supreme Court in *KSR* noted that if the actual application of the technique would have been beyond the skill of one of ordinary skill in the art, then using the technique would not have been obvious.⁵⁸ If any of these findings cannot be made, then this

⁵² 675 F.2d 297, 213 USPQ 532 (CCPA 1982).

⁵³ *Id.* at 301, 213 USPQ at 536.

⁵⁴ 853 F.2d 894, 7 USPQ2d 1573 (Fed. Cir. 1988).

⁵⁵ *Id.* at 903, 7 USPQ2d at 1681.

⁵⁶ 357 F.3d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004).

⁵⁷ 83 USPQ2d 1509 (Bd. Pat. App. & Int. 2007).

⁵⁸ *KSR*, 550 U.S. at __, 82 USPQ2d at 1396.

rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1: The claimed invention in *In re Nilssen*⁵⁹ was directed to a "means by which the self-oscillating inverter in a power-line-operated inverter-type fluorescent lamp ballast is disabled in case the output current from the inverter exceeds some pre-established threshold level for more than a very brief period."⁶⁰ That is, the current output was monitored, and if the current output exceeded some threshold for a specified short time, an actuation signal was sent and the inverter was disabled to protect it from damage.

The prior art (a USSR certificate) described a device for protecting an inverter circuit in an undisclosed manner via a control means. The device indicated the high-load condition by way of the control means, but did not indicate the specific manner of overload protection. The prior art (Kammiller) disclosed disabling the inverter in the event of a high-load current condition in order to protect the inverter circuit. That is, the overload protection was achieved by disabling the inverter by means of a cutoff switch.

The court found "it would have been obvious to one of ordinary skill in the art to use the threshold signal produced in the USSR device to actuate a cutoff switch to render the inverter inoperative as taught by Kammiller."⁶¹ That is, using the known technique of a cutoff switch for protecting a circuit to provide the protection desired in the inverter circuit of the USSR document would have been obvious to one of ordinary skill.

Example 2: The fact pattern in *Ruiz v. AB Chance Co.*⁶² is set forth above in Example 2 in subsection III.A.

The nature of the problem to be solved may lead inventors to look at references relating to possible solutions to that problem.⁶³ Therefore, it would have been obvious to use a metal bracket (as shown in Gregory) with the screw anchor (as shown in Fuller) to underpin unstable foundations.

D. Applying a Known Technique to a Known Device (Method, or Product) Ready for Improvement To Yield Predictable Results

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Office

personnel must then articulate the following:

(1) a finding that the prior art contained a "base" device (method, or product) upon which the claimed invention can be seen as an "improvement";

(2) a finding that the prior art contained a known technique that is applicable to the base device (method, or product);

(3) a finding that one of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results and resulted in an improved system; and

(4) whatever additional findings may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to a known device (method, or product) that was ready for improvement and the results would have been predictable to one of ordinary skill in the art. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1: The claimed invention in *Dann v. Johnston*⁶⁴ was directed towards a system (i.e., computer) for automatic record keeping of bank checks and deposits. In this system, a customer would put a numerical category code on each check or deposit slip. The check processing system would record these on the check in magnetic ink, just as it did for amount and account information. With this system in place, the bank can provide statements to customers that are broken down to give subtotals for each category. The claimed system also allowed the bank to print reports according to a style requested by the customer. As characterized by the Court, "[u]nder respondent's invention, then, a general purpose computer is programmed to provide bank customers with an individualized and categorized breakdown of their transactions during the period in question."⁶⁵

Base System—The nature of the current use of data processing equipment and computer software in the banking industry was that banks routinely did much of the record keeping automatically. In routine check processing, the system read any magnetic ink characters identifying the account and routing. The system also read the amount of the check and then printed that value in a designated area of the check. The check was then sent

through a further data processing step which used the magnetic ink information to generate the appropriate records for transactions and for posting to the appropriate accounts. These systems included generating periodic statements for each account, such as the monthly statement sent to checking account customers.

Improved System—The claimed invention supplemented this system by recording a category code which can then be utilized to track expenditures by category. Again, the category code will be a number recorded on the check (or deposit slip) which will be read, converted into a magnetic ink imprint, and then processed in the data system to include the category code. This enabled reporting of data by category as opposed to only allowing reporting by account number.

Known Technique—This is an application of a technique from the prior art—the use of account numbers (generally used to track an individual's total transactions) to solve the problem of how to track categories of expenditures to more finely account for a budget. That is, account numbers (identifying data capable of processing in the automatic data processing system) were used to distinguish between different customers. Furthermore, banks have long segregated debits attributable to service charges within any given separate account and have rendered their customers subtotals for those charges. Previously, one would have needed to set up separate accounts for each category and thus receive separate reports. Supplementing the account information with additional digits (the category codes) solved the problem by effectively creating a single account that can be treated as distinct accounts for tracking and reporting services. That is, the category code merely allowed what might previously have been separate accounts to be handled as a single account, but with a number of sub-accounts indicated in the report.

The basic technique of putting indicia on data which then enabled standard sorting, searching, and reporting would have yielded no more than the predictable outcome which one of ordinary skill would have expected to achieve with this common tool of the trade and was therefore an obvious expedient. The Court held that "[t]he gap between the prior art and respondent's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art."⁶⁶

⁵⁹ 551 F.2d 1401, 7 USPQ2d 1500 (Fed. Cir. 1988).

⁶⁰ *Id.* at 1402, 7 USPQ2d at 1501.

⁶¹ *Id.* at 1403, 7 USPQ2d at 1502.

⁶² 357 F.3d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004).

⁶³ *Id.* at 1277, 69 USPQ2d at 1691.

⁶⁴ 425 U.S. 219, 189 USPQ 257 (1976).

⁶⁵ *Id.* at 222, 189 USPQ at 259.

⁶⁶ *Id.* at 230, 189 USPQ at 261.

Example 2: The fact pattern in *In re Nilssen*⁶⁷ is set forth above in Example 1 in subsection III.C.

The court found "it would have been obvious to one of ordinary skill in the art to use the threshold signal produced in the USSR device to actuate a cutoff switch to render the inverter inoperative as taught by Kammiller."⁶⁸ The known technique of using a cutoff switch would have predictably resulted in protecting the inverter circuit. Therefore, it would have been within the skill of the ordinary artisan to use a cutoff switch in response to the actuation signal to protect the inverter.

E. "Obvious To Try"—Choosing From a Finite Number of Identified, Predictable Solutions, With a Reasonable Expectation of Success

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Office personnel must then articulate the following:

- (1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem;
- (2) a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem;
- (3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103."⁶⁹ If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1: The claimed invention in *Pfizer, Inc. v. Apotex, Inc.*⁷⁰ was directed to the amlopidine besylate drug product, which is commercially sold in tablet form in the United States under the trademark Norvasc®.

At the time of the invention, amlopidine was known as was the use of besylate anions. Amlopidine was known to have the same therapeutic properties as were being claimed for the amlopidine besylate but Pfizer discovered that the besylate form had better manufacturing properties (e.g., reduced "stickiness").

Pfizer argued that the results of forming amlopidine besylate would have been unpredictable, and therefore were nonobvious. The court rejected the notion that unpredictability could be equated with nonobviousness here, because there were only a finite number (53) of pharmaceutically acceptable salts to be tested for improved properties. The court found that one of ordinary skill in the art having problems with the manufacturability of amlopidine would have looked to forming a salt of the compound and would have been able to narrow the group of potential salt-formers to a group of 53 anions known to form pharmaceutically acceptable salts, which would be an acceptable number to form "a reasonable expectation of success."

Example 2: The claimed invention in *Alza Corp. v. Mylan Laboratories, Inc.*⁷¹ was drawn to sustained-release formulations of the drug oxybutynin in which the drug is released at a specified rate over a 24-hour period. Oxybutynin was known to be highly water-soluble, and the specification had pointed out that development of sustained-release formulations of such drugs presented particular problems.

A prior art patent to Morella had taught sustained-release compositions of highly water-soluble drugs, as exemplified by a sustained-release formulation of morphine. Morella had also identified oxybutynin as belonging to the class of highly water-soluble drugs. The Batchwal prior art patent had taught a sustained-release formulation of oxybutynin that had a different release rate than the claimed invention. Finally, the Wong prior art patent had taught a generally applicable method for delivery of drugs over a 24-hour period. Although Wong mentioned applicability of the disclosed method to several categories of drugs to which oxybutynin belonged, Wong did not specifically mention its applicability to oxybutynin.

The court found that because the absorption properties of oxybutynin would have been reasonably predictable at the time of the invention, there would have been a reasonable expectation of successful development of a sustained-release formulation of oxybutynin as claimed. The prior art, as evidenced by the specification, had recognized the obstacles to be overcome in

development of sustained-release formulations of highly water-soluble drugs, and had suggested a finite number of ways to overcome these obstacles. The claims were obvious because it would have been obvious to try the known methods for formulating sustained-release compositions, with a reasonable expectation of success. The court was not swayed by arguments of a lack of absolute predictability.

Example 3: The claimed invention in *Ex parte Kubin*⁷² was an isolated nucleic acid molecule. The claim stated that the nucleic acid encoded a particular polypeptide. The encoded polypeptide was identified in the claim by its partially specified sequence, and by its ability to bind to a specified protein.

A prior art patent to Valiante taught the polypeptide encoded by the claimed nucleic acid, but did not disclose either the sequence of the polypeptide, or the claimed isolated nucleic acid molecule. However, Valiante did disclose that by employing conventional methods, such as those disclosed by a prior art laboratory manual by Sambrook, the sequence of the polypeptide could be determined, and the nucleic acid molecule could be isolated. In view of Valiante's disclosure of the polypeptide, and of routine prior art methods for sequencing the polypeptide and isolating the nucleic acid molecule, the Board found that a person of ordinary skill in the art would have had a reasonable expectation that a nucleic acid molecule within the claimed scope could have been successfully obtained.

Relying on *In re Deuel*, Appellant argued that it was improper for the Office to use the polypeptide of the Valiante patent together with the methods described in Sambrook to reject a claim drawn to a specific nucleic acid molecule without providing a reference showing or suggesting a structurally similar nucleic acid molecule. Citing *KSR*, the Board stated that "when there is motivation to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." The Board noted that the problem facing those in the art was to isolate a specific nucleic acid, and there were a limited number of methods available to do so. The Board concluded that the skilled artisan would have had reason to try these methods with the reasonable expectation that at least one would be successful. Thus, isolating the

⁶⁷ 851 F.2d 1401, 7 USPQ2d 1500 (Fed. Cir. 1988).

⁶⁸ *Id.* at 1403, 7 USPQ2d at 1502.

⁶⁹ *KSR*, 550 U.S. at ___, 82 USPQ2d at 1397.

⁷⁰ 480 F.3d 1348, 82 USPQ2d 1321 (Fed. Cir. 2007).

⁷¹ 464 F.3d 1286, 80 USPQ2d 1001 (Fed. Cir. 2006).

⁷² 83 USPQ2d 1410 (Bd. Pat. App. & Int. 2007).

specific nucleic acid molecule claimed was "the product not of innovation but of ordinary skill and common sense."

F. Known Work in One Field of Endeavor May Prompt Variations of it for Use in Either the Same Field or a Different One Based on Design Incentives or Other Market Forces if the Variations Would Have Been Predictable to One of Ordinary Skill in the Art

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Office personnel must then articulate the following:

- (1) a finding that the scope and content of the prior art, whether in the same field of endeavor as that of the applicant's invention or a different field of endeavor, included a similar or analogous device (method, or product);
- (2) a finding that there were design incentives or market forces which would have prompted adaptation of the known device (method, or product);
- (3) a finding that the differences between the claimed invention and the prior art were encompassed in known variations or in a principle known in the prior art;
- (4) a finding that one of ordinary skill in the art, in view of the identified design incentives or other market forces, could have implemented the claimed variation of the prior art, and the claimed variation would have been predictable to one of ordinary skill in the art; and
- (5) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claimed invention would have been obvious is that design incentives or other market forces could have prompted one of ordinary skill in the art to vary the prior art in a predictable manner to result in the claimed invention. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1: The fact pattern in *Dann v. Johnston*⁷³ is set forth above in Example 1 in subsection III.D.

The court found that the problem addressed by applicant—the need to give more detailed breakdown by a category of transactions—was closely analogous to the task of keeping track of the transaction files of individual business units.⁷⁴ Thus, an artisan in the data processing area would have recognized the similar class of problem

and the known solutions of the prior art and it would have been well within the ordinary skill level to implement the system in the different environment. The court held that "[t]he gap between the prior art and respondent's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art."⁷⁵

Example 2: The claimed invention in *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*⁷⁶ was directed to a learning device to help young children read phonetically.

The claim read as follows:

An interactive learning device, comprising:

- a housing including a plurality of switches;
- a sound production device in communication with the switches and including a processor and a memory;
- at least one depiction of a sequence of letters, each letter being associable with a switch; and
- a reader configured to communicate the identity of the depiction to the processor, wherein selection of a depicted letter activates an associated switch to communicate with the processor, causing the sound production device to generate a signal corresponding to a sound associated with the selected letter, the sound being determined by a position of the letter in the sequence of letters.

The court concluded that the claimed invention would have been obvious in view of the combination of two pieces of prior art, (1) Bevan (which showed an electro-mechanical toy for phonetic learning), (2) the Super Speak & Read device (SSR) (an electronic reading toy), and the knowledge of one of ordinary skill in the art.

The court made clear that there was no technological advance beyond the skill shown in the SSR device. The court stated that "one of ordinary skill in the art of children's learning toys would have found it obvious to combine the Bevan device with the SSR to update it using modern electronic components in order to gain the commonly understood benefits of such adaptation, such as decreased size, increased reliability, simplified operation, and reduced cost. While the SSR only permits generation of a sound corresponding to the first letter of a word, it does so using electronic means. The combination is thus the adaptation of an old idea or invention (Bevan) using newer technology that is commonly available and understood in the art (the SSR)."

The court found that the claimed invention was but a variation on already known children's toys. This variation

presented no nonobvious advance over other toys. The court made clear that there was no technological advance beyond the skill shown in the SSR device. The court found that "[a]lthough a prior art mechanical device that accomplishes that goal to modern electronics would have been reasonably obvious to one of ordinary skill in designing children's learning devices. Applying modern electronics to older mechanical devices has been commonplace in recent years."

Example 3: The claimed invention in *KSR International Co. v. Teleflex Inc.*⁷⁷ was an adjustable pedal assembly with a fixed pivot point and an electronic pedal-position sensor attached to the assembly support. The fixed pivot point meant that the pivot was not changed as the pedal was adjusted. The placement of the sensor on the assembly support kept the sensor fixed while the pedal was adjusted.

Conventional gas pedals operated by a mechanical link which adjusted the throttle based on the travel of the pedal from a set position. The throttle controlled the combustion process and the available power generated by the engine. Newer cars used computer controlled throttles in which a sensor detected the motion of the pedal and sent signals to the engine to adjust the throttle accordingly. At the time of the invention, the marketplace provided a strong incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for doing so. The prior art (Asano) taught an adjustable pedal with a fixed pivot point with mechanical throttle control. The prior art ('936 patent to Byler) taught an electronic pedal sensor which was placed on a pivot point in the pedal assembly and that it was preferable to detect the pedal's position in the pedal mechanism rather than in the engine. The prior art (Smith) taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's footpad. The prior art (Rixon) taught an adjustable pedal assembly (sensor in the footpad) with an electronic sensor for throttle control. There was no prior art electronic throttle control that was combined with a pedal assembly which kept the pivot point fixed when adjusting the pedal.

The Court stated that "[t]he proper question to have asked was whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading

⁷³ 425 U.S. 219, 189 USPQ 257 (1976).

⁷⁴ *Id.* at 229, 189 USPQ at 261.

⁷⁵ *Id.* at 230, 189 USPQ at 261.

⁷⁶ 485 F.3d 1157, 82 USPQ2d 1687 (Fed. Cir. 2007).

⁷⁷ 550 U.S. ___, 82 USPQ2d 1385 (2007).

Asano with a sensor." ⁷⁸ The Court found that technological developments in the automotive design would have prompted a designer to upgrade Asano with an electronic sensor. The next question was where to attach the sensor. Based on the prior art, a designer would have known to place the sensor on a nonmoving part of the pedal structure and the most obvious nonmoving point on the structure from which a sensor can easily detect the pedal's position was a pivot point. The Court concluded that it would have been obvious to upgrade Asano's fixed pivot point adjustable pedal by replacing the mechanical assembly for throttle control with an electronic throttle control and to mount the electronic sensor on the pedal support structure.

Example 4: The claimed invention in *Ex parte Cotton* ⁷⁹ was a consumer electronics device using bi authentication to authorize sub-users of an authorized credit account to place orders over a communication network up to a pre-set maximum sub-credit limit.

The prior art (Nakano) disclosed a consumer electronics device like the claimed invention, except that security was provided by a password authentication device rather than a bi authentication device. The prior art (Harada) disclosed that the use of a bi authentication device (fingerprint sensor) on a consumer electronics device (remote control) to provide bi authentication information (fingerprint) was known in the prior art at the time of the invention. The prior art (Dethloff) also disclosed that it was known in the art at the time of the invention to substitute bi authentication for PIN authentication to enable a user to access credit via a consumer electronics device.

The Board found that the prior art "shows that one of ordinary skill in the consumer electronic device art at the time of the invention would have been familiar with using bi authentication information interchangeably with or in lieu of PINs to authenticate users." The Board concluded that one of ordinary skill in the art of consumer electronic devices would have found it obvious to update the prior art password device with the modern bi authentication component and thereby gain, predictably, the commonly understood benefits of such adaptation, that is, a secure and reliable authentication procedure.

G. Some Teaching, Suggestion, or Motivation in the Prior Art That Would Have Led One of Ordinary Skill To Modify the Prior Art Reference or To Combine Prior Art Reference Teachings To Arrive at the Claimed Invention

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Office personnel must then articulate the following:

(1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;

(2) a finding that there was reasonable expectation of success; and
(3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success." ⁸⁰ If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

The courts have made clear that the teaching, suggestion, or motivation test is flexible and an explicit suggestion to combine the prior art is not necessary. The motivation to combine may be implicit and may be found in the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. ⁸¹ "[A]n implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the 'improvement' is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance commercial opportunities by improving a product or process is universal—and even common-sensical—we have held that there exists in these situations a motivation to combine prior art references even absent any hint of suggestion in the references themselves. In such situations, the proper question is whether the ordinary artisan possesses knowledge and skills rendering him capable of combining the prior art references." ⁸²

IV. Applicant's Reply

Once Office personnel have established the *Graham* factual findings and concluded that the claimed invention would have been obvious, the burden then shifts to the applicant to (1)

show that the Office erred in these findings, or (2) provide other evidence to show that the claimed subject matter would have been nonobvious. 37 CFR 1.111(b) requires applicant to distinctly and specifically point out the supposed errors in the Office's action and reply to every ground of objection and rejection in the Office action. The reply must present arguments pointing out the specific distinction believed to render the claims patentable over any applied references.

If an applicant disagrees with any factual findings by the Office, an effective traverse of a rejection based wholly or partially on such findings must include a reasoned statement explaining why the applicant believes the Office has erred substantively as to the factual findings. A mere statement or argument that the Office has not established a *prima facie* case of obviousness or that the Office's reliance on common knowledge is unsupported by documentary evidence will not be considered substantively adequate to rebut the rejection or an effective traverse of the rejection under 37 CFR 1.111(b). Office personnel addressing this situation may repeat the rejection made in the prior Office action and make the next Office action final. See MPEP § 706.07(a).

V. Consideration of Applicant's Rebuttal Evidence

Office personnel should consider all rebuttal evidence that is timely presented by the applicants when reevaluating any obviousness determination. Rebuttal evidence may include evidence of "secondary considerations," such as "commercial success, long felt but unsolved needs, [and] failure of others" ⁸³, and may also include evidence of unexpected results. As set forth in section III, above, Office personnel must articulate findings of fact that support the rationale relied upon in an obviousness rejection. As a result, applicants are likely to submit evidence to rebut the fact finding made by Office personnel. For example, in the case of a claim to a combination, applicants may submit evidence or argument to demonstrate that:

- (1) one of ordinary skill in the art could not have combined the claimed elements by known methods (e.g., due to technological difficulties);
- (2) the elements in combination do not merely perform the function that each element performs separately; or
- (3) the results of the claimed combination were unexpected.

⁷⁸ *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.2d 1358, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006).

⁷⁹ *Id.* at 1366, 80 USPQ2d at 1649.

⁸⁰ *Id.* at 1368, 80 USPQ2d at 1651.

⁸³ *Graham v. John Deere Co.*, 383 U.S. at 17, 148 USPQ at 467.

⁷⁸ *Id.* at __, 82 USPQ2d at 1399.

⁷⁹ 83 USPQ2d 1569 (Bd. Pat. App. & Int.

Once the applicant has presented rebuttal evidence, Office personnel should reconsider any initial obviousness determination in view of the entire record.⁸⁴ All the rejections of record and proposed rejections and their bases should be reviewed to confirm their continued viability. The Office action should clearly communicate the Office's findings and conclusions, articulating how the conclusions are supported by the findings. The procedures set forth in MPEP § 706.07(a) are to be followed in determining whether an action may be made final.

See MPEP § 2145 concerning consideration of applicant's rebuttal evidence. See also MPEP § 716 to

§ 716.10 regarding affidavits or declarations filed under 37 CFR 1.132 for purposes of traversing grounds of rejection.

Dated: October 3, 2007.

Jon W. Dudas,
Under Secretary of Commerce for Intellectual
Property and Director of the United States
Patent and Trademark Office.

[FR Doc. E7-19973 Filed 10-9-07; 8:45 am]

BILLING CODE 3510-16-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 08-09]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense
Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104-164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601-3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 08-09 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: October 3, 2007.

L.M. Bynum,
OSD Federal Register Liaison Officer,
Department of Defense.

BILLING CODE 5001-06-M

⁸⁴ See, e.g., *In re Plosecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984); *In re Eli Lilly & Co.*, 90 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990).

APPENDIX E3

02280.002660.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
	:	Examiner: Sharmila S. Gollamudi
Nurhan P. Tutuncu)	
	:	Group Art Unit: 1616
Application No.: 09/825,992)	
	:	Confirmation No. 3697
Filed: April 5, 2001)	
	:	
For: CONFECTIONERY PRODUCT)	
HAVING A SALIVATION REGION	:	
AND AN ORAL COMFORT REGION)	:	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132
OF STEPHEN J. MOSS

Sir:

I, STEPHEN J. MOSS, D.D.S., M.S. declare as follows:

1. I obtained a degree in dentistry from New York University College of Dentistry in 1959.
2. I obtained a Master of Science degree in Biology from New York University Graduate School of Arts and Science in 1962.

3. I have more than forty years experience in the field of dentistry and I am presently a Professor Emeritus at the New York University College of Dentistry.

4. I have published over 200 scientific papers in the area of dentistry and related fields.

5. I am from time to time a consultant to Mars, Incorporated, and I understand that Mars, Incorporated is the assignee of the above captioned application.

6. I have reviewed an Office Action dated February 8, 2007 from the above-captioned application and make this declaration specifically to traverse the factual basis for the statement in the Office Action that either WO 99/589427 (hereinafter "Le") or U.S. Patent No. 4,400,372 (hereinafter "Muhler") teach that acids are antigingivitis agents.

7. Le is cited in the Office Action and, at page 1, lines 21-22, Le references Muhler for the proposition that acid has been "used in chewing gum to soften plaque on teeth."

8. Muhler teaches a chewing gum composition having a combination of acid and abrasive which polishes the teeth. See Muhler, col. 1, lines 11-17. According to Muhler, regular chewing of the composition, as described, polishes the teeth, allowing plaque to be removed, and reducing the rate of dental plaque reformation. See Muhler col. 3, lines 54-59. The purpose of the polishing is to provide a smooth surface that is resistant to plaque and dental calculus reformation. See Muhler, col. 2, lines 9-16, and col. 2, line 67 to col. 3, line 2. Muhler does not teach or suggest that acid by itself removes plaque, but only in combination with an abrasive. See Muhler, col. 3, lines 36-37; col. 5, lines 27-30 and lines 53-55; col. 15, lines 45-47.

9. Le also describes a method of removing or preventing the deposition of plaque on teeth, but as with Muhler, this method comprises regularly chewing a chewing gum comprising a gum base, an abrasive and an acidulent. See Le, page 2, lines 27-28.

10. Muhler is not directed to the treatment of gingivitis, but to a method for removing plaque. Muhler does not disclose the measurement of gingivitis, which would be expected if the patent were directed to a treatment or prevention of gingivitis. Instead, Muhler measures "polishing scores." See Muhler col. 13, line 7 - col. 17, line 22.

11. From the foregoing observations, I conclude that neither Le nor Muhler teaches the use of acid as an anti-gingivitis agent.

12. In my experience, acids are not used as anti-gingivitis agents.

13. Based on my own experience, I believe that acids, of a strength and in an amount that would normally be found in an edible composition, do not have a significant physical or chemical effect on plaque.

14. I understand that one rejection in the February 8, 2007 Office Action is based on U.S. Patent No. 5,284,659 ("Cherukuri") in combination with Le. See page 3 of the Office Action.

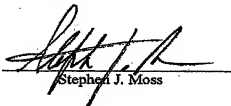
15. According to the Office Action, one would have had a reason to use an acid disclosed in Le in a tablet disclosed in Cherukuri (such as the tablet disclosed in Figures 5 and 6 and described at col. 11, lines 39-44 of Cherukuri) if one "desired to . . . reduce plaque on

teeth." Further according to the Office action, Le teaches that "acids reduce plaque, i.e. having an antigingivitis activity." See page 5 of the Office Action.

16. As I do not believe that acid by itself would remove plaque from teeth or act as an antigingivitis agent, I do not believe that a desire to reduce plaque on teeth would have been a valid reason to combine an acid according to Le in a tablet according to Cherukuri.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Subscribed this 7 day of January, 2008


Stephen J. Moss

APPENDIX E4

BEST AVAILABLE COPY

02280.002660.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)	
	:	Examiner: S. Gollamudi
NURHAN PINAR TÖTÜNCÜ ET AL.)	
	:	Group Art Unit: 1616
Application No.: 09/825,992)	
	:	
Filed: April 5, 2001)	
	:	
For: CONFECTIONERY PRODUCT)	
HAVING A SALIVATION REGION	:	
AND AN ORAL COMFORT REGION)	

Commissioner for Patents
P. O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION OF KEVIN STANTON

I, Kevin Stanton, declare and say that:

1. I am a Product Development Manager and Senior Process Development Engineer at Masterfoods USA and have been in this position since 1998.
2. I graduated from University of California, Davis, with a Master of Science degree in Agricultural Engineering and I have worked in the field of food product development for 16 years.
3. I am one of the named inventors on the above-identified application.

4. I have read the Office Action, dated December 29, 2005, in the above-identified application (hereinafter the "Office Action") and I have read the prior art cited in the Office Action and referenced in the statements herein.

5. I understand that the Office Action, at page 5, asserts that U.S. Patent No. 6,231,900 (hereinafter "Hanke") teaches a composition containing an "orange flavor". I further understand that the Office Action asserts that this ingredient contains orange oil, which is an "essential oil" and that this ingredient is alleged to correspond to or "read on" an oral comfort ingredient selected from the group consisting of lipids, surfactants and mixtures thereof in an amount effective to lubricate, coat or moisten an oral cavity.

6. Lipids, as that term would be understood by one of ordinary skill in the art, generally refers to glycerol esters of fatty acids, which account for ninety-nine percent of lipids of plant and animal origin. See the attached excerpt from Owen R. Fennema, Ed., *Food Chemistry*, Marcel Dekker, Inc. (New York) (1985), p.140.

7. That general understanding is reinforced in the context of the specification of the invention where the lipids that are given as examples are all triacylglycerides, including partially hydrogenated palm kernel oil, medium chain triglycerides, coconut oil, anhydrous milk fat, cocoa butter, corn oil, palm oil, soybean oil, sunflower oil, canola oil and mixtures thereof (see paragraph [0032] of the present application).

8. "Essential oils" do not contain glycerol esters of fatty acids, which are what one of ordinary skill would associate with the word "oils." Rather, essential oils contain a variety of terpenes and oxygenated derivatives, including alcohols, aldehydes,

ketones and esters. Thus, the Examiner is incorrect that an orange oil is a lipid as that term is correctly understood in the context of the specification of the invention.

9. I am familiar with orange flavor and orange oil, and such ingredients are irritants, and they would not have the effect of lubricating, coating or moistening the oral cavity.

10. I believe the Materials Safety and Data Sheet (MSDS) for orange oil, a copy of which is attached hereto, would prevent the ordinarily skilled artisan from using this ingredient to lubricate, coat or moisten the oral cavity. See, for example, Section 3 of the MSDS, where the irritant effects of this ingredient are clearly identified. The Examiner's assertion that an essential oil would be used as an oral comfort ingredient is clearly in error since used in the amounts called for in the present invention, essential oils would be irritant and not oral comfort ingredients.

11. I do not believe that one of ordinary skill in the art would consider "orange oil" to fall within "the group consisting of lipids, surfactants and mixtures thereof," as that phrase would be understood by one of ordinary skill in the art, reading the specification of the present invention.

12. Xerostomia, or dry mouth, is a condition in which insufficient saliva is created in the mouth.

13. The product covered by the pending claims of the subject application was developed at least in part to alleviate xerostomia.

14. Certain claims in the subject application specifically recite a method of treating xerostomia.

15. I understand that the Office Action at pages 6 to 7 states that Hanke teaches "administering a confectionery product comprising two distinct areas of an oral comforting region and a salivation region to the oral cavity to the same population (those with throat irritation, which is a symptom of xerostomia)."

16. The symptoms of cough and cold, including sore throat, are distinct from the symptoms of xerostomia. Sore throat due to cough and cold is generally caused by infection or allergic reaction in the throat, and the symptoms are treated by treating the throat. The symptoms of xerostomia arise from having insufficient saliva in the mouth, and the symptoms are treated by treating the mouth.

17. One of ordinary skill in the art would recognize that administering a soothing composition to the throat of a person suffering from cough and cold symptoms is distinct from administering a salivation agent to the mouth of a person suffering from xerostomia, and that these do not constitute "the same population."

18. For at least the foregoing reasons, Hanke does not teach an oral comfort region, a confectionery containing an oral comfort region and a salivation region, or a method of treating xerostomia with such a confectionery.

19. I have read International Application No. WO 99/59427 (hereinafter "Le"), and I do not understand Le to teach or suggest the concentration of acidulent in a macroscopic region of a confectionery product.

20. I have read U.S. Patent No. 5,284,659 (hereinafter "Cherukuri") and I do not understand Cherukuri to teach the use of acidulents at all, and I especially do not understand that reference to teach or suggest the concentration of acidulent in a macroscopic region of a confectionery product.

21. I do not understand Cherukuri to contain any teaching relevant to promoting salivation.

22. I do not find teaching or suggestion in either Le or Cherukuri that would lead one of ordinary skill in the art to substitute an acidulent, such as taught in Le page 5, lines 13 to 22 for the breath deodorant taught in Cherukuri Table II.

23. For at least the foregoing reasons, I do not consider that it would have been "obvious" in view of Cherukuri and Le to formulate a product having two discrete regions, wherein acidulent is concentrated in one region in an amount effective to enhance salivation, and wherein an oral comfort ingredient selected from lipids, surfactants and mixtures thereof, is concentrated in the other of the two regions.

24. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Subscribed this 1st day of May, 2006.


Kevin Stanton

APPENDIX E5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
	:	Examiner: Sharmila S. Gollamudi
Nurhan P. Tutuncu)	
	:	Group Art Unit: 1616
Application No.: 09/825,992)	
	:	
Filed: April 5, 2001)	
	:	
For: CONFECTIONERY PRODUCT)	
HAVING A SALIVATION REGION	:	
AND AN ORAL COMFORT REGION)		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132
OF DONALD L. MAYER

Sir:

DONALD L. MAYER declares and says that:

1. I am employed by Mars, Incorporated as an independent consultant in the area of consumer response and customer service.
2. I have received a B.S. degree from the University of Evansville and an M.B.A. degree in Information Management from Iona College.
3. I have more than thirty years of experience in the management of consumer response call banks and in the analysis of consumer response data.

4. I am familiar with the AQUADROPS® Hydrating Mouth Drops product and the consumer response data which is referenced in this Declaration.

5. I understand that the above-captioned application has claims that cover the AQUADROPS® Hydrating Mouth Drops product, and that all of the claims have been rejected by the U.S. Patent and Trademark Office as allegedly being obvious in view of certain prior art.

6. This Declaration is made in support of the non-obviousness of the present claims on the grounds that the product provided certain customers with unusual or unexpected drymouth relief, evidenced by the consumer call-in data presented herein.

7. In the years 2003-2007, consumer call-in data was collected pursuant to standard practice in this industry. In the period covered by this study, over 12,000 unsolicited calls were taken and logged in the U.S. in connection with the AQUADROPS® Hydrating Mouth Drops product. Summary data pertaining to these calls is attached hereto as Exhibit 1.

8. Pursuant to a standard practice, customer comments are taken down verbatim, and are assigned categories, such as "like," "dislike," and "where to buy."

9. Where consumers commented on the functionality of the product, its ability to hydrate, cause salivation, or its ability to relieve dry mouth, this information was also taken down verbatim, and key words recorded.

10. An unusually high number of the calls received in connection with the AQUADROPS® Hydrating Mouth Drops product (389 in total, including negative comments) commented on the functionality of the product to cause hydration, salivation or

relieve drymouth. A summary of the calls having verbatim remarks relating to hydrating effect, salivation effect or drymouth are attached at Tab 2.

11. Based on my years of experience reviewing similar data, I consider the nature of the responses in these consumer calls to be unusually specific, with a high proportion of calls relating to the functionality of the product.

12. These responses indicate that the AQUADROPS® Hydrating Mouth Drops product was perceived by consumers as performing functionally in a way that was noticeably different from other products on the market, and that could not be replicated or substituted by other products on the market.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Subscribed this 5 day of May, 2008

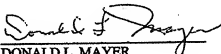

DONALD L. MAYER

EXHIBIT 1

Aqua Drops Consumer Care Data

	2003	2004	2005-2007
Where-to-buy	225	1,475	8,107
Like product	112	491	329
Dislike product	24	115	21
Ideas	20	102	46
Other	144	912	538
Totals	525	3,095	9,041

EXHIBIT 2

Sort of AQUADROPS® CONSUMER DATA: ALL COMMENTS CONTAINING TEXT STRINGS "hydrat", "saliva", OR "dry mouth"

Received	Subject	Verbatim	Qty
6/7/2005	BRINGBK	AQUA DROPS SUGAR FREE HYDRATING MINTS	1
7/18/2005	BRINGBK	THESE WERE GREAT FOR DRY MOUTH PLEASE BRING THEM BACK	1
8/23/2005	BRINGBK	BRING BACK THE PRODUCT IT THE ONLY THING THAT HELPS DRY MOUTH	1
8/30/2005	BRINGBK	BRING BACK THE AQUA DROPS THEY HELP WITH DRY MOUTH	1
8/30/2005	BRINGBK	PLEASE BRING BACK THE PRODUCT IT HELPS WITH THE DRY MOUTH	1
9/15/2005	BRINGBK	WHERE CAN I FIND THE PRODUCT MY HUSBAND LIKES THIS FLAVOR AND FOUND IT VERY HYDRATING	1
9/19/2005	BRINGBK	SUGAR FREE VARIETY GAGS HER AND DONT HELP WITH THE DRY MOUTH WHY CANT WE KEEP THEM AS A REGULAR PRODUCT	1
10/18/2005	BRINGBK	BRING BACK THE PRODUCT IT WAS THE BEST THING FOR DRY MOUTH	1
10/19/2005	BRINGBK	WANTS US TO BRING THEM BACK IF NO LONGER AVAILABLE	1
11/9/2005	BRINGBK	BRING BACK THE PRODUCT IT WAS THE BEST THING FOR DRY MOUTH	1
11/9/2005	BRINGBK	SHE AND HER HUSBAND NEED THEM FOR THEIR DRY MOUTH	1
11/9/2005	BRINGBK	WIFE USES AQUA DROPS FOR MEDICALLY NEEDED HYDRATION	1
11/21/2005	BRINGBK	WONDERFUL PRODUCT RELIEVES HER DRY MOUTH AND FRESHENS HER BREATH ONLY PRODUCT SHE FOUND THAT WORKS FOR HER	1
11/28/2005	BRINGBK	I RECOMMEND THIS TO PATIENTS WITH DRY MOUTH	1
12/1/2005	BRINGBK	WE ARE INTERESTED IN FINDING OUT MORE ON YOUR PRODUCT AS OUR PATIENTS HAVE CHRONIC DRY MOUTH	1
12/14/2005	BRINGBK	IS THERE A WAY I CAN GET THESE SHIPPED TO ME THEY ARE THE ONLY THING THAT WORKS FOR DRY MOUTH	1
12/14/2005	BRINGBK	CANT FIND AQUADROPS HYDRATING MINTS	1
12/21/2005	BRINGBK	WHERE CAN I FIND THEM THEY ARE VERY HELPFUL FOR HIS WIFES DRY MOUTH	1
12/21/2005	BRINGBK	DRY MOUTH RELIEF THANKS FOR MAKING THEM	1
12/28/2005	BRINGBK	I AM TAKING CHEMOTHERAPY AND IT IS A GREAT PRODUCT TO PROVIDE MOISTURE IN MY DRY MOUTH WHERE CAN I BUY IT	1
1/7/2006	BRINGBK	MY MOM HAS TROUBLE MAKING SALIVA WILL THIS HELP	1
1/20/2006	BRINGBK	HELP ME FIND AQUADROPS TO HELP WITH THE SIDE EFFECT OF DRY MOUTH FROM CHEMOTHERAPY	1
1/27/2006	BRINGBK	CANT FIND AQUADROPS SUGAR FREE HYDRATING MINTS	1
1/31/2006	BRINGBK	WANTS TO KNOW IF THERE IS ANY PLACE SHE CAN BUY THEM HUSBAND USES FOR HIS DRY MOUTH FROM CHEMO	1
2/7/2006	BRINGBK	THIS PRODUCT HELPED WITH HER DRY MOUTH	1
2/9/2006	BRINGBK	THE BEST PRODUCT I HAVE EVER USED FOR DRY MOUTH	1
2/13/2006	BRINGBK	ONLY PRODUCT THAT HELPS WITH HER DRY MOUTH WANTS TO KNOW WHAT HAPPENED TO THEM	1
2/15/2006	BRINGBK	THIS HELPED WITH DRY MOUTH AND WANTS IT RETURNED	1
2/15/2006	BRINGBK	PLEASE BRING THIS BACK IT HELPED WITH DRY MOUTH	1
2/23/2006	BRINGBK	PLEASE BRING BACK PRODUCT VERY HELPFUL FOR PEOPLE WITH MEDICATIONS AND DRY MOUTH FROM THE SIDE EFFECTS OF MEDICATIONS	1
2/27/2006	BRINGBK	GREAT RELIEF FROM MED INDUCED DRY MOUTH USING PRODUCT	1
3/22/2006	BRINGBK	HAS NOT FOUND ANYTHING ELSE THAT WORKED WELL WITH HER DRY MOUTH LIKE AQUADROPS AND CANT FIND THEM ANYWHERE	1
3/23/2006	BRINGBK	CANT FIND AQUADROPS HYDRATING MINTS	1
3/23/2006	BRINGBK	WHERE CAN I FIND THEM THEY ARE HELPFUL FOR HER MOTHERS DRY MOUTH	1
3/28/2006	BRINGBK	HAD CHRONIC DRY MOUTH AND WANTS THESE BACK ON THE MARKET	1
3/31/2006	BRINGBK	THESE HELPED WITH HER DRY MOUTH AND WANTS THEM BACK ON THE MARKET	1
3/31/2006	BRINGBK	WHERE CAN I FIND THEM HIS WIFE NEEDS THEM FOR DRY MOUTH	1
4/5/2006	BRINGBK	THESE HELPED WITH HER DRY MOUTH WITH HER MEDS	1
4/11/2006	BRINGBK	THESE WORKED GREAT FOR DRY MOUTH	1
4/21/2006	BRINGBK	WORKED GREAT FOR DRY MOUTH	1
4/21/2006	BRINGBK	THIS PRODUCT HELPED WITH DRY MOUTH	1
4/28/2006	BRINGBK	WHERE CAN I FIND THEM THEY HELP WITH MY DRY MOUTH	1
5/2/2006	BRINGBK	SAYS THIS HELPED WITH HER MEDS AND DRY MOUTH	1
5/5/2006	BRINGBK	THIS HELPED HIS WIFE WITH HER MEDS AND DRY MOUTH	1
5/10/2006	BRINGBK	BEST PRODUCT I HAVE FOUND TO COMBAT DRY MOUTH DURING PUBLIC SPEAKING	1
5/10/2006	BRINGBK	THESE HELPED WITH HER DRY MOUTH DUE TO HER MEDS	1
5/15/2006	BRINGBK	WHERE CAN I FIND ANY VARIETY THEY WORKED WONDERFUL WITH DRY MOUTH	1
5/18/2006	BRINGBK	PLEASE KEEP MARKETING AQUADROPS SO THE OTHER DRY MOUTH SUFFERERS AND MYSELF CAN HAVE SOME RELIEF WITH THIS PRODUCT	1
5/19/2006	BRINGBK	HELPED WITH HER DRY MOUTH WHILE TAKING HER MEDS	1
5/23/2006	BRINGBK	WHERE CAN I FIND THEM IN MY AREA THEY HELP WITH MY DRY MOUTH	1
5/23/2006	BRINGBK	HELPED WITH HER DRY MOUTH	1
5/25/2006	BRINGBK	I HAVE DRY MOUTH AND THEY ARE THE ONLY THINGS I CAN TOLERATE AND THEY WORK	1
5/25/2006	BRINGBK	HELPED WITH HER DRY MOUTH	1
5/28/2006	BRINGBK	LOVED THIS PRODUCT BECAUSE IT HELPED WITH HER DRY MOUTH	1
5/31/2006	BRINGBK	WAS TRYING TO FIND THIS PRODUCT IT HELPED WITH DRY MOUTH	1
6/1/2006	BRINGBK	THIS HELPED WITH HER DRY MOUTH	1
6/1/2006	BRINGBK	HELPED WITH HER DRY MOUTH	1
6/2/2006	BRINGBK	THESE HELPED WITH HER DRY MOUTH	1

Received	Subject	Verbatim	Qty
8/2/2006	BRINGBK	THESE HELPED WITH HER DRY MOUTH	1
8/2/2006	BRINGBK	THIS HELPED WITH HIS DRY MOUTH BECAUSE OF HIS MEDS	1
8/5/2006	BRINGBK	HELPED WITH HER DRY MOUTH	1
8/8/2006	BRINGBK	THIS HELPED WITH HER DRY MOUTH	1
8/12/2006	BRINGBK	WHERE CAN I FIND THESE IN MY AREA MY WIFE USES THEM FOR DRY MOUTH	1
8/13/2006	BRINGBK	HELPED WITH HER DRY MOUTH	1
8/13/2006	BRINGBK	DEVASTED BECAUSE I CANT FIND THEM ANYMORE TAKES MEDICATION THAT CAUSES DRY MOUTH	1
8/15/2006	BRINGBK	THIS HELPED WITH HER DRY MOUTH WHILE TAKING HER MEDS	1
8/15/2006	BRINGBK	THE BEST THING SHE EVER HAD FOR DRY MOUTH BRING IT BACK	1
8/19/2006	BRINGBK	LOOKING FOR AQUA DROPS I HAVE SEVERE DRY MOUTH FROM MEDICATIONS	1
8/20/2006	BRINGBK	MY MOTHER USES THEM AND SHE SUFFERS FROM DRY MOUTH	1
8/20/2006	BRINGBK	THEY HELP MY DRY MOUTH	1
8/21/2006	BRINGBK	WHERE CAN I FIND AQUA DROPS I HAVE A VERY DRY MOUTH FROM SOME MEDICATION	1
8/22/2006	BRINGBK	THIS HELPED WITH HER DRY MOUTH DUE TO HER MEDS	1
8/23/2006	BRINGBK	I AM SO SAD THAT YOU HAVE DISCONTINUED AQUADROPS AS A PATIENT I FOUND THE PRODUCT	1
8/23/2006	BRINGBK	WAS WONDERFUL FOR DRY MOUTH	1
8/23/2006	BRINGBK	COULD YOU PLEASE BRING THEM BACK THEY HELP VERY MUCH WITH DRY MOUTH	1
8/23/2006	BRINGBK	STATED THESE HELPED WITH DRY MOUTH	1
8/23/2006	BRINGBK	THIS HELPED WITH HER DRY MOUTH	1
8/28/2006	BRINGBK	THIS HELPED WITH HER DRY MOUTH DUE TO MEDS	1
8/28/2006	BRINGBK	THIS HELPED WITH HER DRY MOUTH WHILE SHE WAS TAKING HER MEDS	1
8/28/2006	BRINGBK	LOVED THIS PRODUCT AND HELPED WITH DRY MOUTH	1
8/28/2006	BRINGBK	WHY CANT I FIND THEM ANYMORE THEY WERE GREAT FOR DRY MOUTH	1
8/30/2006	BRINGBK	THIS PRODUCT HELPED WITH HER DRY MOUTH DUE TO HER MEDS	1
7/5/2006	BRINGBK	WHY CANT I FIND THEM THEY ARE GREAT FOR DRY MOUTH	1
7/7/2006	BRINGBK	THIS PRODUCT HELPED WITH HER DRY MOUTH	1
7/10/2006	BRINGBK	I HAVE A DRY MOUTH PROBLEM AND CANT FIND AQUA DROPS	1
7/13/2006	BRINGBK	CANT FIND THEM ANYWHERE THEY WERE GREAT FOR DRY MOUTH AND DRY COUGH	1
7/19/2006	BRINGBK	LOVES THE PRODUCT AND WANTS IT BACK TO HELP WITH HER DRY MOUTH DUE TO HER AUTO	1
7/27/2006	BRINGBK	IMAGINE DISORDER	1
7/28/2006	BRINGBK	ARE YOU EVER GOING TO BRING THEM BACK HELPS WITH DRY MOUTH AND SOAR THROAT	1
8/2/2006	BRINGBK	WHY CANT WE FIND THEM THEY WERE GREAT FOR DRY MOUTH	1
8/9/2006	BRINGBK	BRING THEM BACK I NEED THEM FOR MY DRY MOUTH	1
8/9/2006	BRINGBK	WHERE CAN I FIND AQUA DROPS MY MOTHER HAS A DRY MOUTH AND NEEDS THEM	1
8/17/2006	BRINGBK	WHERE CAN I FIND THEM IN MY AREA HELPED WITH MY DRY MOUTH	1
8/18/2006	BRINGBK	CANT FIND THEM AND I AM A DESPERATE 83 YR OLD WOMAN WITH A DRY MOUTH CONDITION THEY	1
8/22/2006	BRINGBK	ARE THE ONLY THING THAT WORKS	1
8/22/2006	BRINGBK	I WANT THIS PRODUCT BACK FOR MY WIFE WHO HAS NO SALIVA GLANDS IT WAS THE BEST	1
9/5/2006	BRINGBK	DO YOU STILL MAKE AQUA DROPS SUGAR FREE HYDRATING MINTS	1
9/6/2006	BRINGBK	LOVE THEM THEY REALLY HELP WITH MY DRY MOUTH CONDITION WHERE CAN I FIND THEM	1
9/21/2006	BRINGBK	I HAVE NOT BEEN ABLE TO GET THESE IN MY AREA THEY WERE GREAT FOR MY DRY MOUTH	1
9/25/2006	BRINGBK	PLEASE BRING THEM BACK THEY WERE GREAT FOR DRY MOUTH	1
10/16/2006	BRINGBK	CANT FIND THEM MEDICATIONS CAUSE DRY MOUTH	1
10/16/2006	BRINGBK	WHY CANT I FIND THEM ANYMORE THEY ARE GREAT FOR DRY MOUTH DUE TO MEDICATIONS	1
10/17/2006	BRINGBK	WHERE CAN I FIND THEM AREA THEY ARE GREAT FOR DRY MOUTH	1
10/18/2006	BRINGBK	PLEASE DO NOT STOP MAKING YOUR AQUADROPS THEY ARE A LIFESAVER FOR PEOPLE WHO	1
10/18/2006	BRINGBK	HAVE A DRY MOUTH	1
10/23/2006	BRINGBK	PLEASE BRING THEM BACK THEY WERE GREAT FOR MY MOTHERS DRY MOUTH	1
10/24/2006	BRINGBK	ARE THEY GOING TO COME BACK OUT OR IS THERE ANOTHER HYDRATING PRODUCT	1
10/30/2006	BRINGBK	WANTS THIS PRODUCT BACK BECAUSE OF DRY MOUTH	1
11/6/2006	BRINGBK	HAS DRY MOUTH AND WOULD LIKE TO KNOW WHERE TO FIND THEM	1
11/6/2006	BRINGBK	WANTS THIS PRODUCT BROUGHT BACK FOR CHRONIC DRY MOUTH PROBLEMS	1
11/6/2006	BRINGBK	CAN YOU PLEASE BRING THIS PRODUCT BACK I NEED IT FOR MY DRY MOUTH	1
12/4/2006	BRINGBK	BRING PRODUCT BACK IT IS A GOOD PRODUCT FOR PEOPLE WITH DRY MOUTH FROM	1
12/13/2006	BRINGBK	MEDICATIONS	1
12/28/2006	BRINGBK	REALLY HELPED WITH DRY MOUTH AND CANT FIND THEM ANYWHERE	1
12/28/2006	BRINGBK	I REALLY WOULD LIKE TO BUY SOME MORE FOR MY DRY MOUTH PROBLEM BUT I CANT FIND ANY IN	1
12/28/2006	BRINGBK	THE STORES AROUND HERE WHERE I LIVE	1
2/12/2007	BRINGBK	PLEASE BRING BACK AQUA DROPS US OLDER PEOPLE NEED IT TO SOOTHE OUR DRY MOUTH	1
2/15/2007	BRINGBK	HAS DRY MOUTH DUE TO RADIATION AND THIS PRODUCT REALLY HELPS	1
2/21/2007	BRINGBK	I AM A SIX YEAR CANCER SURVIVOR AND WOULD LOVE TO HAVE THIS PRODUCT BACK ON THE	1
2/22/2007	BRINGBK	MARKET AS MY SALIVA GLANDS ARE RUINED	1
2/27/2007	BRINGBK	REALLY LIKED THE PRODUCT BECAUSE MEDICATION SHE IS ON GIVES HER DRY MOUTH	1
2/27/2007	BRINGBK	WANTS THEM BROUGHT BACK FRIEND IS UNDER GOING RADIATION THERAPY AND THEY WORK	1
3/1/2007	BRINGBK	WONDERS FOR THE SIDE AFFECTS VERY DRY MOUTH	1
3/1/2007	BRINGBK	BRING BACK AQUA DROPS WE RECOMMEND THEM FOR OUR PATIENTS WITH DRY MOUTH	1
3/1/2007	BRINGBK	PROBLEMS	1

Received	Subject	Verbatim	Qty
		CANCER SURVIVORS REALLY NEED THIS PRODUCT BROUGHT BACK PEOPLE THAT HAVE HEAD AND MOUTH RADIATION LOOSE THE ABILITY TO CREATE ANY SALIVA THERE IS NO OTHER PRODUCT ON THE MARKET THAT HELPS AS CANCER SURVIVORS WE NEED THIS BACK AS QUICKLY AS POSSIBLE PLEASE	1
3/22/2007	BRINGBK	I WANT THIS PRODUCT BACK IT IS GOOD FOR MY DRY MOUTH	1
3/29/2007	BRINGBK	LOOKING FOR AQUA DROPS PLEASE BRING THE PRODUCT BACK SHE HAS A DISEASE THAT DOES NOT ALLOW HER TO CREATE SALIVA AND IT HELPED HER A GREAT DEAL	1
4/6/2007	BRINGBK	WOULD LIKE THIS PRODUCT BROUGHT BACK FOR THOSE THAT HAVE CHRONIC DRY MOUTH PROBLEMS	1
4/6/2007	BRINGBK	I HAVE DRY MOUTH AND WOULD LOVE SEEING THESE BACK AS THEY HELP	1
4/10/2007	BRINGBK	CAROL FROM SAN FRANCISCO AQUA DROPS SHE HAS A SEVERE HYDRATING PROBLEM AND THIS IS THE ONLY PRODUCT ON THE MARKET THAT HELPS HER SHE HAS ONLY 1 LEFT SHE HAS TMJ AND CANNOT CHEW GUM	1
4/24/2007	BRINGBK	WHERE CAN I FIND THESE THEY REALLY HELPED MY DRY MOUTH	1
5/2/2007	BRINGBK	PLEASE BRING BACK THE AQUA DROPS THEY ARE GOOD FOR DRY MOUTH	1
5/11/2007	BRINGBK	BRING IT BACK SHE TAKES MEDICATION AND THAT IS THE ONLY THING THAT HELPED HER DRY MOUTH FROM HER MEDS	1
5/14/2007	BRINGBK	WHERE CAN I FIND THESE AQUA DROPS THEY REALLY HELP MY DRY MOUTH	1
6/1/2007	BRINGBK	PLEASE BRING BACK THE PRODUCT BROTHER IS DIABETIC AND LOVED IT FOR DRY MOUTH	1
7/8/2007	BRINGBK	PLEASE BRING THIS PRODUCT BACK AS THERE ARE MANY PEOPLE WITH ILLNESSES THAT CAUSE DRY MOUTH AND THIS PRODUCT WAS IDEAL FOR IT	1
7/9/2007	BRINGBK	IS ON MEDICATION AQUA DROPS WERE THE ONLY THINGS THAT HELPED HER DRY MOUTH	1
7/27/2007	BRINGBK	MY PULMONARY GROUP LOVED THEM BECAUSE THEY REALLY HELPED DRY MOUTH BRING THEM BACK	1
7/31/2007	BRINGBK		1
8/4/2004	BUY	want to order a case have dry mouth from depression from medicine	1
10/14/2003	CANTFIND	where can i find them they are wonderful help with my dry mouth after taking medication	1
12/10/2003	CANTFIND	where can i find them have chronic dry mouth	1
1/23/2004	CANTFIND	where can i buy i have cancer and i very dry mouth	1
3/3/2004	CANTFIND	husband is a cancer patient and discovered the aqua drops i cannot find them anywhere and he only has one pkg left. he has been relying on them for dry mouth	1
3/6/2004	CANTFIND	cant find them looked in grocery stores on lipitor and it gives you dry mouth this works great	1
3/10/2004	CANTFIND	have ecgrins and this is the best for my dry mouth	1
3/15/2004	CANTFIND	where can i find these my husband has throat cancer and his saliva gland was destroyed.	1
3/26/2004	CANTFIND	believe you make a product called AquaDrops Hydrating Mints i am in the United States How may i get mints	1
4/26/2004	CANTFIND	cant find in my area daughter sent from VA helps my husband he gets dry mouth	1
5/3/2004	CANTFIND	have so many patients with dry mouth i have not seen Aqua Drops yet in our area. Do you have samples	1
6/1/2004	CANTFIND	son uses for dry mouth cant find anymore tried cvs target walgreens eckert	1
8/9/2004	CANTFIND	i live in the Kansas City MO area and was able to find them at a WalMart Dad had throat cancer and these helped hydrate him	1
8/23/2004	CANTFIND	where can i find these they help me with my dry mouth syndrome	1
9/14/2004	CANTFIND	many of my medications cause dry mouth so your products sound great but i called every store in the area and no one carry your product i live in Milwaukee Wisconsin	1
9/20/2004	CANTFIND	trying to find for my mother she has dry mouth from medication	1
10/21/2004	CANTFIND	has Sjogren Syndrome no saliva or moisture in body cant find product	1
11/17/2004	CANTFIND	great product really works with dry mouth from cancer treatments	1
11/30/2004	CANTFIND	daughter gave her aqua drops for dry mouth helps where can she buy them here cant find	1
1/5/2005	CANTFIND	CANT FIND THESE THEY REALLY HELP WITH DRY MOUTH	1
2/2/2005	CANTFIND	REALLY LIKES THESE FOR DRY MOUTH WHERE CAN I FIND THEM	1
4/27/2005	CANTFIND	CANT FIND AQUA DROPS I AM ON MEDICATION IT HELPS MY DRY MOUTH	1
5/3/2005	CANTFIND	CANNOT FIND THEM IN MY AREA FOR CHEMOTHERAPY PATIENT HAS NO SALIVARY GLANDS	1
7/13/2005	CANTFIND	UNABLE TO GET LOCALLY AND NEEDS THEM FOR A MEDICAL CONDITION THAT GIVES HER SEVER DRY MOUTH	1
7/15/2005	CANTFIND	CANT FIND CANDIES ANY MORE AQUADROPS IN ANY FLAVOR REALLY HELP THE DRY MOUTH CAUSED BY MEDICATIONS	1
9/6/2005	CANTFIND	CAN YOU PLEASE TELL ME WHERE I CAN GET YOUR PRODUCT MY HUSBAND HAS NO SALIVA GLANDS THAT WORK SINCE HIS CANCER RADIATION FOR ORAL CANCER AND LOVES THEM	1
6/29/2004	DISFLV	I found it's mint flavor weak and hydrating part of the mint disgusting	1
11/11/2004	DISFLV	the candies tasted awful and it gave her dry mouth	1
8/28/2003	DISPROD	pkg is misleading it says aqua which means water also any mint would hydrate and increase saliva i think this product is beneath you	1
9/15/2003	DISPROD	did not hydrate my mouth	1
10/1/2003	DISPROD	don't like the taste of it does not help my dry mouth do take medication	1
11/5/2003	DISPROD	don't like them didnt hydrate my mouth and the flavor should be sweeter not what i thought they would be there is no water in them almost died they actually dehydrate only sugar and corn syrup do you have a dictionary for hydrate false advertisement	1
11/11/2003	DISPROD	tasted horrible and not hydrating at all	1
11/17/2003	DISPROD	did not hydrate me	1
11/21/2003	DISPROD	just terrible tasting no hydrating effect by the time i drove 5 miles i had dry mouth again and a terrible taste in my mouth	1

Received	Subject	Verbatim	Qty
12/9/2003	DISPROD	did not provide hydration	1
12/29/2003	DISPROD	sorry to report that the AquaDrops are less than satisfactory The dark blue side Instant Hydration was especially disgusting	1
1/15/2004	DISPROD	don't like them they don't do what you say about instant hydration and there is no last effect	1
2/18/2004	DISPROD	does not hydrate my mouth and feels like it make throat tick	1
2/24/2004	DISPROD	the drops are not hydrating and it doesn't taste like a mint more like a cough drop like medicine	1
3/26/2004	DISPROD	does not hydrate as good as I thought	1
4/5/2004	DISPROD	they don't hydrate as good as a tick tac	1
4/8/2004	DISPROD	these are just as hydrating as any other hard candy and don't even taste good	1
5/19/2004	DISPROD	didn't notice mouth being any more hydrated though flavor is refreshing	1
5/24/2004	DISPROD	aqua drops did not hydrate my body	1
5/25/2004	DISPROD	just found that they do not hydrate they just create saliva	1
6/1/2004	DISPROD	first time I have tried them they taste gross and don't hydrate my mouth	1
6/14/2004	DISPROD	didn't hydrate at all	1
7/2/2004	DISPROD	candies did not instantly hydrate me not lasting refreshment	1
7/28/2004	DISPROD	I did not feel hydrated or refreshed I had a nasty taste in my mouth and a sticky feeling that would not go away for a while after I would never buy them again and I wouldn't even eat another one	1
7/27/2004	DISPROD	these do not hydrate me I am still dehydrated	1
8/3/2004	DISPROD	did seem to hydrate as you said it would	1
8/4/2004	DISPROD	have tried them 3 x don't care for it as they don't hydrate me and they don't taste good	1
8/30/2004	DISPROD	not very strong and don't keep mouth hydrated	1
9/29/2004	DISPROD	does not hydrate like you say it does	1
10/18/2004	DISPROD	did not like the taste did not hydrate mouth consumer wants replacement with money	1
11/5/2004	DISPROD	Likes them a lot but this time same flavor but no hydration no lasting	1
11/29/2004	DISPROD	Dissatisfied because hydration did not last too long	1
12/2/2004	DISPROD	it tastes good but shouldn't be advertised as hydration	1
12/17/2004	DISPROD	doesn't help at all with dry mouth makes you thirstier	1
12/22/2004	DISPROD	said it is not an instant hydration and will not buy it again	1
3/22/2005	DISPROD	CONSUMER DOES NOT LIKE THE PRODUCT SAYS IT DID NOT HELP HER WITH HER DRY MOUTH	1
4/22/2005	DISPROD	DOESNT REALLY STIMULATE SALIVATION IT FEELS KIND OF GUMMY AND DOESNT LIKE THE MINT FLAVOR	1
4/25/2005	DISPROD	DISAPPOINTED WITH PRODUCT DID NOT HYDRATE	1
7/31/2005	DISPROD	USED YOUR PRODUCT WHILE IN ISREAL DESERT AND GOT DEHYDRATED YOUR BOX SAYS IT HYDRATES	1
10/12/2005	DISPROD	THEY WERE NOT REFRESHING OR HYDRATING IN MY PERSONAL OPINION	1
10/27/2005	DISPROD	WANTS TO BE REIMBURSED BECAUSE DENTIST TOLD NOT TO TAKE THEM NOT GOOD FOR DRY MOUTH BECAUSE OF THE SUGAR AND SYRUPS IN THEM	1
12/1/2005	DISPROD	THE PACKAGE GIVES THE IMPRESSION THAT THE AQUA DROP WOULD QUICKLY DISSOLVE TO HYDRATE MY MOUTH THEY DONT	1
7/31/2003	LIKE	keeps grandma hydrated helps her vertigo also Its great my husband got a sample at a convention	1
8/27/2003	LIKE	the best wonderful Ive been on oxygen for 10 yrs and this is the first time I have felt real relief from dry mouth I had both flavors	1
8/29/2003	LIKE	they are perfect for my cancer patients who suffer from dry mouth	1
9/4/2003	LIKE	the best for dry mouth	1
9/17/2003	LIKE	product is great cancer patient and has dry mouth every since kemo	1
9/23/2003	LIKE	they are great my mother is being treated for cancer of the throat and they work just great to hydrate her mouth	1
10/2/2003	LIKE	enjoyed the mouthwatering experience and thought this would be a good product for her patients with dry mouth symptom	1
10/3/2003	LIKE	they are wonderful I suffer from dry mouth due to medications and these really work and last a long time	1
10/7/2003	LIKE	they are great my dentist recommended them I suffer from dry mouth	1
10/20/2003	LIKE	we love them They are very tasty and wonderful for dry mouth	1
10/20/2003	LIKE	great product really works for dry mouth can you make it sugar free	1
10/22/2003	LIKE	love for my mother for dry mouth	1
10/28/2003	LIKE	love them they definitely hydrate your mouth shes a smoker and drinks coffee and it is amazing how well they work	1
10/30/2003	LIKE	love them really helps my dry mouth	1
11/1/2003	LIKE	they are wonderful for me I suffer from shogrens syndrome and these work to keep my mouth hydrated	1
11/11/2003	LIKE	great product really helps with my dry mouth where can I buy more	1
11/18/2003	LIKE	loved them for lines of dry mouth have a disease	1
11/21/2003	LIKE	great product for dry mouth	1
11/21/2003	LIKE	I have MS medication aqua drops really relieved my dry mouth	1
11/25/2003	LIKE	love them for my dry mouth	1
11/26/2003	LIKE	really help her dry mouth have used professional things nothing compares to this product	1
12/8/2003	LIKE	wonderful great for people who suffer from dry mouth or if you have to present in front of people	1
12/15/2003	LIKE	these are great im a singer and they really help keep my throat hydrated for long performances	1
12/15/2003	LIKE	love them for dry mouth	1
12/18/2003	LIKE	these deal with dry mouth perfectly	1
12/24/2003	LIKE	singers paradise hydrates throat and recommend to others please continue to make	1
12/29/2003	LIKE	love them with dry mouth	1

Received	Subject	Verbatim	Qty
		best I ever found for instant hydration I am a tongue cancer survivor and suffer from dry mouth these are marvelous	1
12/30/2003	LIKE	these are the only thing that cures the medical condition dry mouth	1
1/6/2004	LIKE	really help with my dry mouth	1
1/6/2004	LIKE	these are so good they help me with my dry mouth	1
1/7/2004	LIKE	am so excited that you came out with this product it helps me with my dry mouth while I am on chemotherapy	1
1/7/2004	LIKE	really great for dry mouth	1
1/9/2004	LIKE	love them for my dry mouth	1
1/9/2004	LIKE	I love these they taste great and do hydrate your mouth	1
1/12/2004	LIKE	love them for my dry mouth	1
1/13/2004	LIKE	like them for my dry mouth	1
1/15/2004	LIKE	we really like them they are so good for people on medication and for dry mouth	1
1/19/2004	LIKE	I appreciate these they help cure my dry mouth	1
1/20/2004	LIKE	really love them for my dry mouth	1
1/23/2004	LIKE	love the hydration effect for my dry mouth	1
1/27/2004	LIKE	bought citrus flavor by mistake really only wanted mint package says hydrating mints	1
1/27/2004	LIKE	love them for my dry mouth	1
1/28/2004	LIKE	they are the best they do hydrate end last longer than other mint types of candy	1
2/2/2004	LIKE	this is a great product really great for dry mouth syndrome	1
2/13/2004	LIKE	love them for my dry mouth	1
2/16/2004	LIKE	best for my dry mouth	1
2/23/2004	LIKE	great product I had cancer lost my saliva glands	1
3/1/2004	LIKE	I love the great flavor of these and they really do hydrate my mouth	1
3/1/2004	LIKE	help with dry mouth caused by radiation	1
3/1/2004	LIKE	great product really helps with my dry mouth but they are very hard to find	1
3/1/2004	LIKE	really enjoy these are a remedy for dry mouth	1
3/4/2004	LIKE	I absolutely love these I talk a lot during the day and they keep mouth hydrated and fresh	1
3/8/2004	LIKE	I like the way these hydrate your mouth	1
3/8/2004	LIKE	have soggins from Lur's love these for my dry mouth	1
3/8/2004	LIKE	really like these they help my dry mouth	1
3/10/2004	LIKE	these are wonderful for dry mouth relief	1
3/10/2004	LIKE	they are wonderful for dry mouth relief	1
3/11/2004	LIKE	love them for my dry mouth take medication it works	1
3/12/2004	LIKE	so good for dry mouth	1
3/15/2004	LIKE	cant find them husband has soggins dry mouth	1
3/23/2004	LIKE	they are the best for my dry mouth	1
3/25/2004	LIKE	love them husband dry mouth taking medication	1
3/25/2004	LIKE	love them have continuous dry mouth always carry a water bottle	1
3/25/2004	LIKE	these are amazing truly instantaneous hydration	1
4/1/2004	LIKE	thank you so much I haven't felt this hydrated in 5 years	1
4/5/2004	LIKE	they are refreshing as well as hydrating	1
4/5/2004	LIKE	it does what it says hydrates dont need gum any more	1
4/7/2004	LIKE	great product really helps with my dry mouth	1
4/9/2004	LIKE	tried and everyone at one turned on to them good because take alot medication and cant chew gum for dry mouth	1
4/14/2004	LIKE	they are absolutely wonderful they help my dry mouth	1
4/15/2004	LIKE	they are the only thing I have found so far that helps dry mouth	1
4/15/2004	LIKE	I like them they seem to work I suffer from a dry mouth problem I have tried many different products	1
4/22/2004	LIKE	they work great in hydrating my mouth	1
4/28/2004	LIKE	great product IMMEDIATELY my mouth was rehydrated and refreshed it was almost like being in a commercial	1
4/29/2004	LIKE	love the mint flavor for my dry mouth	1
4/29/2004	LIKE	really helps with my dry mouth can you send a coupon	1
5/3/2004	LIKE	great product really helps with dry mouth	1
5/3/2004	LIKE	constantly dehydrated these are extremely helpful to me	1
5/5/2004	LIKE	I suffer from dry mouth aqua drops really help	1
5/10/2004	LIKE	pretty good idea and they are good its just that once they leave your mouth they dont continue to hydrate	1
5/10/2004	LIKE	unless you drink gatorade with it	1
5/10/2004	LIKE	suffer from dry mouth they are great	1
6/11/2004	LIKE	love them for dry mouth	1
6/17/2004	LIKE	aqua drops are dream come true for my dry mouth	1
7/1/2004	LIKE	these have really helped with my dry mouth and throat	1
7/12/2004	LIKE	great product really helps with my dry mouth show this product to my doctor	1
7/16/2004	LIKE	these are great suffer from dry mouth and these are fantastic had mint and citrus	1
8/4/2004	LIKE	I'm a diabetic this really helps to hydrate my mouth but they are very hard to find	1
8/5/2004	LIKE	these are really good and they work for my dry mouth	1
8/12/2004	LIKE	suffer with dry mouth this product is a life saver	1
8/27/2004	LIKE	they are wonderful help me with my dry mouth symptom	1
8/30/2004	LIKE	aqua drops they are fabulous take medication and I have dry mouth	1
9/2/2004	LIKE	great product really helps my dry mouth	1
9/7/2004	LIKE	great product really helps my dry mouth	1

Received	Subject	Verbatim	Qty
9/8/2004	LIKE	I love them for my dry mouth that was inherited from my mother	1
9/15/2004	LIKE	like them for my dry mouth	1
9/15/2004	LIKE	like them very much for taste have dry mouth from medication and the fact it is sugar free	1
9/16/2004	LIKE	love them for my dry mouth the greatest	1
9/21/2004	LIKE	great product really helps with my dry mouth	1
9/21/2004	LIKE	really helps with my dry mouth very hard to find in kaufman tx	1
9/27/2004	LIKE	great product really helps with my dry mouth	1
10/8/2004	LIKE	they are so helpful with my dry mouth syndrome	1
10/12/2004	LIKE	I just love them they really work to hydrate your mouth	1
10/13/2004	LIKE	really likes them they help with dry mouth	1
10/25/2004	LIKE	is on medication has dry mouth problems product helps a lot	1
10/28/2004	LIKE	wanted to tell you how great these Aquadrops are I suffer from a constantly dry mouth and these make my mouth feel soooooo much better	1
11/1/2004	LIKE	really like them for his dry mouth at night time	1
11/2/2004	LIKE	help me immensely take lot of meds and have chronic dry mouth this is great	1
11/2/2004	LIKE	has to take medication so she gets dry mouth these help a lot	1
11/3/2004	LIKE	colled to praise aquadrops how much the soldiers in Iraq love them hydrates their mouth	1
11/3/2004	LIKE	the product is very good for the diabetic people they should do more marketing in the health web sites and	1
11/8/2004	LIKE	other so people that have a serious dry mouth can purchase them	1
11/28/2004	LIKE	My husband uses them for his dry mouth they are very helpful	1
11/28/2004	LIKE	they work for dry mouth she takes a lot of medication likes all the flavors	1
11/30/2004	LIKE	these are her favorite flavor they are great for her dry mouth	1
12/3/2004	LIKE	they're great for hydration	1
12/8/2004	LIKE	likes them because they are very good for her dry mouth	1
12/14/2004	LIKE	likes it alot helps her dry mouth	1
1/26/2005	LIKE	LIKE THE PRODUCT BECAUSE IT IS EVERY GOOD FOR HER DRY MOUTH	1
1/31/2005	LIKE	LOVES THE PRODUCT IT HELPED HER DRY MOUTH	1
2/1/2005	LIKE	LIKES IT HELPS DRY MOUTH	1
2/5/2005	LIKE	CONSUMER LOVES THE PRODUCT PREVENTS HIM FROM DRY MOUTH	1
2/4/2005	LIKE	CONSUMER LOVES THE PRODUCT IT HELPS HER WITH DRY MOUTH	1
2/4/2005	LIKE	CONSUMER LOVES THE PRODUCT HELPS WITH DRY MOUTH	1
2/8/2005	LIKE	AQUA DROPS HELP WITH THEIR DRY MOUTH	1
2/8/2005	LIKE	LOVES THE MINTS AND THEY REALLY DO HYDRATE LIKE ADVERTISED	1
2/8/2005	LIKE	LOVES THE HYDRATION IT PROVIDES	1
2/9/2005	LIKE	YOUR PRODUCT IS THE FIRST THAT HAS GIVEN MUCH RELIEF FOR MY DRY MOUTH THANK YOU SO MUCH	1
2/9/2005	LIKE	I HAVE DIABETES AQUA DROPS REALLY HELP WITH MY DRY MOUTH	1
2/19/2005	LIKE	LIKES THE PRODUCT HELPS HER WITH DRY MOUTH	1
2/23/2005	LIKE	WANT TO THANK YOU FOR INVENTING AQUA DROPS I JUST STARTED TAKING A PRESCRIPTION THAT CAUSES ME TO BE VERY DEHYDRATED AND HAVING AQUA DROPS ON HAND IS VERY HELPFUL	1
2/28/2005	LIKE	THANK YOU AQUADROPS HAVE A MEDICAL CONDITION THAT I TAKE ALOT OF MEDS FOR A MAJOR SIDE EFFECT IS DRY MOUTH	1
2/28/2005	LIKE	CONSUMER LOVES THE PRODUCT HELPS WITH DRY MOUTH	1
3/1/2005	LIKE	CONSUMER LIKES THE PRODUCT HELPS HER WITH DRY MOUTH	1
3/8/2005	LIKE	CONSUMER REALLY LIKES THE PRODUCT AND IT KEEPS HER FROM HAVING DRY MOUTH	1
3/14/2005	LIKE	THESE HELP WITH THE DRY MOUTH SHE GETS FROM HER RADIATION TREATMENT	1
3/21/2005	LIKE	THESE ARE GREAT THEY ARE HYDRATING	1
3/21/2005	LIKE	SHE LIKES THAT THEY HELP HER WITH HER DRY MOUTH	1
4/2/2005	LIKE	CONSUMER LIKES THE PRODUCT IT HELPS HER WITH THE DRY MOUTH	1
4/14/2005	LIKE	WORKS FOR A PSYCHOLOGICAL OFFICE AND DEALS WITH PATIENTS WHO HAVE FREQUENT DRY MOUTH AND THIS PRODUCTS WORKS GREAT FOR THEM	1
4/21/2005	LIKE	CONSUMER LIKES THE PRODUCT FOR HER DRY MOUTH	1
4/27/2005	LIKE	LOVE AQUADROPS IT HELPS MY DRY MOUTH	1
4/27/2005	LIKE	LOVE THEM BECAUSE I HAVE DRY MOUTH PROBLEMS	1
4/28/2005	LIKE	LIKE THE PRODUCT FOR DRY MOUTH	1
5/2/2005	LIKE	THEY ARE THE BEST THING FOR A DRY MOUTH	1
5/3/2005	LIKE	LIKE PRODUCT VERY REFRESHING AND HYDRATING	1
5/4/2005	LIKE	LOVES THE PRODUCT HELPS WITH HER MEDICAL CONDITION THAT GIVES HER A DRY MOUTH	1
5/31/2005	LIKE	I REALLY LIKE THE PRODUCT ESPECIALLY HOW IT HELPS MY DRY MOUTH MEDICAL CONDITION I LOVE AQUA DROPS MY HUSBAND USES YOUR PRODUCT EVERY DAY DUE TO THE DRY MOUTH HE GETS WITH CERTAIN MEDICATIONS	1
6/16/2005	LIKE	THIS PRODUCT IS ALL THAT HELPED HER DRY MOUTH	1
6/16/2005	LIKE	AQUA DROPS ARE AWESOME I WAS SO IMPRESSED. THEY REALLY DO HYDRATE YOUR MOUTH AND KEEP IT FRESH	1
6/28/2005	LIKE	MY MOTHER LIKES THE PRODUCT IT HELPS WITH HER DRY MOUTH DUE TO A MEDICAL CONDITION	1
7/5/2005	LIKE	THESE ARE REALLY HELPFUL FOR ME BECAUSE I HAVE DRY MOUTH FROM MEDICATION	1
8/3/2005	LIKE	WRITING TO TELL YOU HOW MUCH I APPRECIATE YOUR PRODUCT WORK WITH PATIENTS WHO HAVE A VARIETY OF DISORDERS WHICH OFTEN RESULT IN DRY MOUTH NECK AND THROAT CANCER	1
8/4/2005	LIKE		1

Received	Subject	Verbatim	Qty
8/11/2005	LIKE	MY HUSBAND LIKES THE PRODUCT ESPECIALLY FOR THE HYDRATION IT PROVIDES	1
8/28/2005	LIKE	CONSUMER LOVES THE PRODUCT IT HELPS HER WITH HER DRY MOUTH	1
9/8/2005	LIKE	I REALLY LIKE THE PRODUCT WITH MY MEDICAL CONDITION I CANNOT DRINK A LOT OF WATER AND THIS PRODUCT HELPS WITH HYDRATION	1
9/12/2005	LIKE	THESE TASTE GREAT AND REALLY STIMULATE THE SALIVARY GLANDS	1
9/12/2005	LIKE	YOUR PRODUCT IS WONDERFUL I RECOMMEND IT TO MY CHEMO PATIENTS TO HELP WITH DRY MOUTH	1
9/12/2005	LIKE	I LIKE THE PRODUCT ESPECIALLY THE HYDRATING EFFECT	1
9/13/2005	LIKE	THEY SAVE MY LIFE DURING RADIATION TREATMENTS FOR CANCER BY KEEPING MY MOUTH HYDRATED I LOVE THEM	1
10/3/2005	LIKE	SHE LIKES THEM BECAUSE THEY ARE HELPFUL WITH HYDRATING HER MOUTH DURING CHEMOTHERAPY	1
10/26/2005	LIKE	want for my patients love them for dry mouth	1
10/15/2003	SAMPLE	tried your product and found it to be very effective in refreshing a dry mouth. I want to recommend it to the dialysis patients that I counsel.	1
12/10/2003	SAMPLE	many of our patients suffer from dry mouth as a side effect of medication Bone Marrow Transplant clinic	1
1/12/2004	SAMPLE	registered nurse in a busy oncology practice our patients experience very dry mouths would really like to know if you could possibly send us some samples	1
1/18/2004	SAMPLE	mental health agency where we prescribe psychotropic medications which cause dry mouth Would it be possible to get samples	1
1/18/2004	SAMPLE	counsel dialysis patients who suffer from dry mouth can you send samples	1
1/23/2004	SAMPLE	always looking for hydrating help for their patients with dry mouths due to medication side effects or those who have fluid restrictions	1
2/2/2004	SAMPLE	I am a Dental Hygienist with many patients who suffer from dry mouth symptoms can you send samples	1
2/18/2004	SAMPLE	glutelin that works with people on hemodialysis Part of their dietary restrictions include limiting fluid intake	1
3/2/2004	SAMPLE	thirst and dry mouth are major issues any samples	1
3/5/2004	SAMPLE	do you have any samples for patients have with dry mouth	1
3/17/2004	SAMPLE	patients really liked them they helped greatly with their dry mouth syndrome would like samples	1
3/19/2004	SAMPLE	wondering if you provide samples so we can promote product in our office for people with dry mouth.	1
3/31/2004	SAMPLE	urologists office would like samples to give to patients to treat symptoms of dry mouth after medication	1
4/1/2004	SAMPLE	dental hygienist I am always interested in products to help relieve dry mouth for some of my patients Do you offer any free samples	1
4/23/2004	SAMPLE	I am a dentist with patients complaining of dry mouth could we have samples	1
4/28/2004	SAMPLE	Dental Assistant, working with Indigent HIV/AIDS patients who often get Dry Mouth syndrome from their medications and wonder if you have on SAMPLES	1
4/28/2004	SAMPLE	I work for a dialysis center we are always looking for ways to help our patients who suffer from dry mouth can you send samples	1
6/7/2004	SAMPLE	see numerous CA patients in our practice could we be sent samples to give for dry mouth	1
6/10/2004	SAMPLE	Center for Liver Diseases patients are treated with a medication that sometimes causes dry mouth. Do you ever provide samples	1
6/17/2004	SAMPLE	Dentist looking for products for pts with dry mouth	1
7/22/2004	SAMPLE	would like to receive samples along with coupons for my patients. Dialysis patients have to limit how much fluid they drink each day and often suffer from dry mouth	1
7/27/2004	SAMPLE	Aquadrops for chemotherapy patients These mints are wonderful for promoting salivation Is it possible to receive samples of these to give to our patients	1
8/12/2004	SAMPLE	hospice nurse these are great for patients on chemo and radiation who suffer from dry mouth I haven't found anything better	1
8/13/2004	SAMPLE	samples to give to our oral cancer patients with dry mouth problems	1
8/20/2004	SAMPLE	work with patients that suffer from xerostomia dry mouth we have been recommending aqua drops do you have samples	1
8/23/2004	SAMPLE	MAY I HAVE SOME FREE SAMPLES FOR PATIENTS WITH DRY MOUTH	1
9/29/2004	SAMPLE	can you send samples or coupons for my patients complaining of dry mouth	1
10/7/2004	SAMPLE	DO WE HAVE ANY SAMPLES AVAILABLE THEY HAVE ALOT OF PATIENTS WITH DRY MOUTHS	1
1/27/2005	SAMPLE		1

X. Related Proceedings Appendix

There are no related appeals or proceedings.

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